

are included in CTs so that drugs can be properly studied. It may be preliminary to make conclusions about female representation in phase I clinical trials because it is not mandatory to register all phase I trials on [clinicaltrials.gov](http://clinicaltrials.gov), but further investigation will be conducted into FDA summary reports. Preliminary findings indicate that efforts to include female subjects may be effective in the subset of studies that reported their results. As of 2017, 51.3% of the U.S. population over 18 years old is female (U.S. Census Bureau). Early clinical trials often help to establish safety and dosing for phase III trials. Thus, it is pertinent that the inclusion rate is reflective of the general population at all clinical trial stages, not just pivotal, phase III trials. It would be prudent to monitor this trend as more studies report their results. Given that the average US life expectancy is now 78 years and that elderly population is expected to double in coming decades (NIH, 2016), there is an urgent need to include this population in current and future clinical research. Geriatrics, particularly those age 75+, use more than a third of total prescription and over-the-counter medications sold in US (Merck Institute, 2014), but is severely underrepresented in CTs. The effects of polypharmacy and changes in drug metabolism with age increase the need for specific drug dosage recommendations for geriatrics. As there was no discernable difference in drug labels fulfilling areas examined before and after 2015, FDASIA implementation may not have impacted geriatric inclusion in CT for drugs approved between 2010 to 2017. As many of these CTs began prior to FDASIA 2012 signing and 2015 implementation, the legislation's full impact may occur in future years. Nonetheless, inadequate language currently found in geriatric drug labels can create challenges for clinicians when prescribing these medications for geriatric patients, potentially contributing to adverse drug events.

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### Assessing Research Activity and Capacity of Community Based Organizations: Field Testing of the Community Research Activity Assessment Tool (CREAT)

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**OBJECTIVES/SPECIFIC AIMS:** 1. To assess the acceptability and feasibility and of an online self-assessment version of the Community REsearch Activity Assessment Tool (CREAT), an instrument to measure research capacity of CBOs. 2. To elicit CBO perspectives on their research and knowledge generation activities. **METHODS/STUDY POPULATION:** Thirteen CBOs who had previously partnered with an academic course on practice-based community health research were contacted and asked to participate in the field testing of the CREAT and provide feedback on areas of strength and areas for potential improvement. Eleven organizations completed the field testing, which began and ended with an in-person semi-structured interview with the online self-administration of the CREAT in the middle. The semi-structured interviews were audio-recorded with questions pertaining to topics such as: strengths and challenges of previous academic research partnerships, perceptions around the importance of research within the organization, thoughts and reactions to the CREAT, and general feedback about the CREAT. Results from the self-administered CREAT were used to test a scoring algorithm. Semi-structured interviews are being transcribed, pre-post responses to questions of strengths and challenges in

engaging in research partnerships will be compared, and overall qualitative transcripts will be coded using grounded theory. **RESULTS/ANTICIPATED RESULTS:** Anticipated Results: The CREAT was acceptable and self-administration was feasible. Average time for completion of the online CREAT was  $41 \pm 13$  min, and respondents did not need assistance from the interviewer to complete the online instrument. Suggestions for improvements focused on word choices and scale options. Respondents were aware of the importance of research activities for their CBOs, particularly for optimizing programmatic quality and services. Access to staff and financial resources were key barriers to strengthening research capacity, and respondents noted that engaging in research partnerships can also bring in additional resources. Interview transcription is still in progress along with the refinement of the codebook for the qualitative data collected. In alignment with objectives/goals outlined above, the results will be separated into the following four sections: CBO Research and Knowledge Generation Activities, Acceptability of the Tool, Feasibility of the Tool, and Refinement of the Tool. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The online, self-administered CREAT instrument is acceptable and feasible for CBO respondents. Availability of a validated tool to assess research capacity of CBOs, developed and refined with input from community researchers, will support targeted research capacity building for CTsAs, community organizations and partners, thus strengthening collaborations. Translational scientists, public health systems and community health improvement depend on CBOs as partners in community-engaged research (CEnR). The CREAT will allow community members to more fully contribute their expertise to the development, implementation and evaluation of interventions, and to develop more equitable partnerships with researchers.

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### Building Capacity for Community Engaged Research: Penn State University's Faculty Fellowship Program

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**OBJECTIVES/SPECIFIC AIMS:** To build capacity for community engaged, translational research in faculty across the university. **METHODS/STUDY POPULATION:** Each year, the Community Engagement Research Core (CERC) of the Penn State CTSI invites applications for one to two Community Engagement Faculty Fellowships. Applicant teams are comprised of a junior or mid-level investigator seeking to expand their work into the CEnR arena under the mentorship of a senior investigator with expertise in community engaged scholarship. The fellow must develop a plan for the mentoring year, including a timeline, activities to be undertaken together, knowledge to be acquired, deliverables, and a budget. The funding supports two course releases or the clinical equivalent for the fellow, and a small budget to support the mentor's research program. Proposals are evaluated using NIH scientific merit criteria. **RESULTS/ANTICIPATED RESULTS:** We are in our second year of the fellowship program. Two highly qualified fellows are currently working with established community-based mentors. The 2017-2018 fellowship team showcases how an effective mentor-fellow partnership can help move a fellow's work along the translational spectrum.

By working with her mentor, our first fellow's research has expanded from basic discovery science in a university hospital to development of a neonatal intensive care unit intervention to be employed with parents in the community. The 2018-2019 scholar, who utilized the community engagement research core (CERC) of the PSU CTSI in preparation of a PCORI grant, has since received the PCORI award and is working with her mentor to bring her innovative mental health screenings to the public schools. We are currently evaluating applications for the third year of the program, and please to have engaged applicants from across several Penn State campuses and disciplines. **DISCUSSION/SIGNIFICANCE OF IMPACT:** The fellowship is enjoying early success in terms of fellow productivity, expanding translational research expertise, and fueling interest across the Penn State campuses in community engagement research. Future work will focus on sustainability planning for this type of program, metrics for tracking success, and plans for integrating fellows into a growing community of engaged scholars at the university.

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### Cardiovascular Health Promotion Among African-Americans: Community Participatory Approach to Design an Innovative Mobile-Health Intervention

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**OBJECTIVES/SPECIFIC AIMS:** To translate a behavioral theory-informed, evidence-based, face-to-face health education program into an mHealth lifestyle intervention for African-Americans (AAs). **METHODS/STUDY POPULATION:** This mixed methods study consisted of 4 phases, using an iterative development process to intervention design with the AA community. In Phase 1, we held focus groups with AA community members and church partners (n=23) to gain insight regarding the needs and preferences of potential app end users. In Phase 2, the interdisciplinary research team synthesized input from Phase 1 for preliminary app design and content development. Phase 3 consisted of a sequential 3-meeting series with the church partners (n=13) for iterative app prototyping (assessment, cultural tailoring, final review). Phase 4 was a single group pilot study among AA church congregants (n=50) to assess app acceptability, usability, and satisfaction. **RESULTS/ANTICIPATED RESULTS:** Phase 1 focus groups indicated preferences for general and health related apps: multifunctional; high-quality graphics/visuals; evidence-based, yet simple health information; and social networking capability. Phase 2 integrated these preferences into the preliminary app prototype. Feedback from Phase 3 was used to refine the FAITH! App prototype for pilot testing. Phase 4 pilot testing indicated high acceptability, usability, and satisfaction of the FAITH! App. **DISCUSSION/SIGNIFICANCE OF IMPACT:** This study illustrates the process of using formative and CBPR approaches to design a culturally relevant, mHealth lifestyle intervention to address CV health disparities within the AA community. Given the positive perceptions of the app, our study supports the use of an iterative development process by others interested in implementing an mHealth lifestyle intervention for racial/ethnic minority communities.

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### Clinic-Level Factors and Retention in Care among People Living with HIV (PLWH) in a United States (US) Multi-Site Cohort, 2010-2016

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**OBJECTIVES/SPECIFIC AIMS:** The National HIV/AIDS strategy aims to increase retention in care (RIC) to reduce HIV transmission and mortality. Previous studies have evaluated clinic-level interventions such as appointment reminders and peer navigation. However, few studies have investigated the association between multiple clinic-level factors and RIC among PLWH across the United States. We conducted a multi-site cohort study to identify clinic-level factors associated with RIC in the United States from 2010-2016. **METHODS/STUDY POPULATION:** We included PLWH with at least one HIV primary care visit from 2010-2016 at seven sites of the Center for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS). Individual-level data collected as part of routine clinical care were abstracted from the electronic health record. Clinic-level data were gathered through a survey and included questions on site characteristics (i.e. clinic volume) as well as services available at the site during each year of the study: peer navigation, RIC posters/brochures, laboratory test timing, flexible scheduling, appointment reminder types, and stigma support services defined as intensive HIV education and advocacy regarding support to address stigma at outreach visits. RIC was defined as  $\geq 2$  encounters per year,  $\geq 90$  days apart, observed until death, administrative censoring (December 31, 2016), or loss to follow-up (no visit for  $> 12$  months with no future visits). Poisson panel regression with robust error variance, clustering by site and adjusting for calendar year, age (modeled with a cubic spline), sex, race/ethnicity, and HIV transmission risk factor, was used to estimate incident rate ratios (IRR) with 95% confidence intervals (CI) for RIC. Clustering by site has been shown to absorb for clustering that could occur at the individual level as well. **RESULTS/ANTICIPATED RESULTS:** Among 21,046 patients contributing 103,348 person-years, 67% of person-years were RIC. Text appointment reminders (IRR = 1.13; 95% CI: 1.03-1.24) and stigma support services (IRR=1.11; 95% CI: 1.04-1.19) were significantly associated with RIC. RIC disparities in individual-level patient characteristics were observed even after accounting for clinic-level characteristics. Older patients were more likely to be RIC demonstrated through year comparisons due to the use of a spline; for age 50 years (IRR = 1.07, 95% CI: 1.06-1.08) and 60 years (IRR = 1.15, 95% CI: 1.13-1.17) compared to 45 years. Female PLWH were more likely to be RIC compared to males (IRR = 1.03, 95% CI: 1.02-1.05) and Hispanic PLWH were more likely to be RIC compared to white, non-Hispanic PLWH (IRR = 1.09, 95% CI: 1.05-1.13). Although commonly found to be associated with worse RIC, Black race and injection drug use were not associated with RIC in this population. **DISCUSSION/SIGNIFICANCE OF IMPACT:** In this multi-site US cohort study from 2010-2016, availability of text appointment reminders and stigma support services at a clinic were associated with approximately 10% higher probability of RIC than at clinics without those services. RIC disparities persisted with respect to individual-level characteristics of age, sex, and race/ethnicity even after accounting for these clinic-level factors. Prospective studies