

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, 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 ± 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.