sessions were 1 hour, and 15 minutes. Exams given post class session with a mean score of 22.8/30 for session 1 and a mean score of 23.80/30 for session 2. RESULTS/ANTICIPATED RESULTS: The Community Research Academy (CRA) has thus far held for two sessions. Of the 45 enrollees, 20 completed the entire program. Of those, ten have joined the CAB board; and three have actively participated in the pilot award review process. One of the CRA graduates will be publishing her photo novella assignment in Health Affairs. One person changed careers,: and several people have taken all the classes for a second time. Many participants originally came from our faith-based connections. Now word of mouth is expanding the program. DISCUSSION/SIGNIFICANCE: Community engagement ensures that the fresh voices of diverse populations are involved in translational science. Their input ultimately leads to creating novel clinical innovations; such community-driven ingenuity which addresses the deeply felt needs of those communities.

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Meeting the Needs of Transgender People through Community Engagement

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OBJECTIVES/GOALS: Alachua TranQuility was formed in early 2016 to address needs of transgender people in Alachua County, Florida and surrounding areas. Increasing awareness of gender identity issues created a growing population in need of additional health and social services to counter the negative health outcomes traditionally experienced by transgender people. METHODS/STUDY POPULATION: The group met monthly at UF HealthStreet, a CTSA community engagement program, where social and medical referrals and opportunities to participate in research were made available to attendees. Those attending included transgender and gender non-conforming individuals as well as family, friends and other allies. Outreach was conducted through social media, physical fliers, and tabling at community events. TranQuility partnered with local LGBTQ organizations to promote activities. Leadership was provided by a steering committee that changed over time, with feedback from attendees guiding planning. Simultaneous to TranQuilitys founding, a Youth Gender Clinic was established at UF Health, clearly demonstrating the need for services aimed at the transgender population. RESULTS/ANTICIPATED RESULTS: Between February 2016 and September 2019, attendance at meetings was logged per HealthStreet protocols. Age of attendees ranged from 10 to 75, and most were non-Hispanic whites. More than 300 individuals attended meetings across time, and many attended multiple meetings, with greater than 15% having attended five or more meetings. Attendance averaged around 30+ each month, with a high of 76. Educational programming was offered, such as information on hormone therapy and name/gender marker change, and a parent support group was formed to meet concurrently with the main group. Social opportunities were very popular, as a safe place for people to present as their authentic selves. The coronavirus pandemic curtailed in-person meetings at HealthStreet in 2020, but the group plans to return to this format in 2022. DISCUSSION/SIGNIFICANCE: TranQuility has become an established organization to which other groups provide referrals. Qualitatively it is clear that many people have been positively impacted. An ongoing discussion for the group, however, has been to improve outreach to transgender people of color, who typically suffer from the most discrimination and anti-trans violence.

Regulatory Science

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Enhancing Research Ethics, Equity and Protections for Uninsured Study Participants

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OBJECTIVES/GOALS: To increase diversity in clinical and translational research (CTR), to strengthen protections for uninsured and under-insured study participants from vulnerable groups by addressing their medical, ancillary care and psycho-social needs and to develop a systematic ethically sound approach to addressing such needs in the study protocol and budget. METHODS/STUDY POPULATION: We conducted) ethical analyses of: (1) the regulatory and ethics scholarship concerning protections and duty of care to research participants from vulnerable groups, and 2) arguments concerning the nature and scope of ancillary care obligations of researchers, as well as 3) a review of the applicable local, federal, and international regulations and practices concerning the duty of care to CTR participants and potential participants who are uninsured, under-insured and/or undocumented members of vulnerable groups. RESULTS/ANTICIPATED RESULTS: Uninsured and underinsured study participants pose major ethical challenges for CTR as medical needs arising during a study are usually covered by the participants own insurance. Lack of health insurance increases vulnerability and creates (1) a barrier to research participation for members of socially disenfranchised groups, (2) risk of discriminatory exclusion of such participants from clinical studies, and (3) inter-institutional inconsistencies in meeting their medical needs; thus limiting diversity in CTR. To address the challenges, we propose an inclusive, systematic, ethically sound approach, which deliberately plans for and provides resources within a study protocol to address the medical and psycho-social needs of uninsured participants during and beyond the study. DISCUSSION/SIGNIFICANCE: Including diverse participants in CTR ensures data quality and social justice. PIs and IRBs should adopt an inclusive approach to the medical needs of vulnerable uninsured participants, plan for their medical and ancillary care needs in the protocol and budget, list community resources, provide follow-up support and note assistance in their files.

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Ethical Considerations of Decentralized Clinical Trials

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OBJECTIVES/GOALS: Our goal is three-fold: (1) to enhance protections for research participants in decentralized clinical trials (DCT) by (2) identifying the ethical and regulatory challenges posed by DCT and (3) considering possible solutions to the ethical and regulatory challenges of DCT. METHODS/STUDY POPULATION: A literature review was conducted to identify the ethical and regulatory challenges of DCT. The review showed that, with few exceptions, the publications on DCT have been written by IT experts, researchers or representatives of the pharma industry. There are hardly any independent or multidisciplinary analyses of DCT, e.g., by ethicists, medical sociologists or patients. This suggests that, currently, the

https://doi.org/10.1017/cts.2022.93 Published online by Cambridge University Press