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## **Duke Research at Pickett: The Evolution of a Free-standing Research Site Partnering with Communities Toward Health Equity Advancement**

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## **Abstract**

While clinical research intends to improve health outcomes for all, access to research participation is often limited and inequitable. Geographic proximity is a recognized barrier, thus, systemic infrastructure solutions through federal programs including General Clinical Research Centers and Clinical and Translational Science Awards have sought to improve accessibility. Even with such support, academic medical centers often have limited clinical research-dedicated space apart from shared exam rooms in difficult-to-navigate hospitals or clinics. In 2019, the Duke University School of Medicine looked beyond its medical center campus to identify free-standing sites within Durham communities for participant study visits. Catalyzed by the COVID-19 pandemic, Duke Research at Pickett, a 22 000-square-foot building with a laboratory, 30 exam rooms, and onsite parking, opened in October 2020 to support vaccine and treatment trials. Upon the lifting of many COVID-19 restrictions, and in partnership with the Research Equity and Diversity Initiative (READI) Community Advisory Council, the building was transformed to encourage community gatherings, education, and training programs. To date, Duke Research at Pickett has hosted 2692 participants in 78 research trials and 14 community-engaged activities.

## Introduction

Ensuring equitable access to research is critical to ensure new medical discoveries are translatable to all people. However, this can be affected by many factors including the convenience and accessibility of locations, community trust in research and associated medical providers, and a myriad of other social factors (1, 2). National Institutes of Health (NIH) funded systematic approaches for providing dedicated research spaces have included the longstanding General Clinical Research Center Program and an expansion in 2006 to focus on additional opportunities to improve accessibility via the Clinical and Translational Science Awards (CTSA) Program. In 2012, the transformative vision of the Institute of Medicine (IOM) committee placed heavy emphasis on community engagement throughout the research continuum, beginning with active and substantial community participation. Among other needs to facilitate community engagement, the IOM cited infrastructure development in universities and communities as one key input to successfully meet the long-term goal of improving population health. This represents an evolutionary integration of support for physicians, researchers, and communities working together to move health research from bench to community with the underlying goal of increasing access to participation in clinical research (3). However, with this notable attention and available funding, accessibility to research for many individuals remains a barrier.

Barriers to participation in research are multifactorial and span from sociological to logistical. Most research is conducted within academic medical centers that often require paying for parking, navigating complex healthcare systems, and waiting in clinical spaces that may not feel safe or comfortable for many community members. Underserved racial and ethnic groups are often underrepresented in clinical research due to lack of invitation or exclusion from research, mistrust of research and healthcare institutions, and social factors (4). Logistical and financial barriers to research participation including significant time commitments, and costs relating to transportation, missed work, and child care, all impede attempts to improve inclusivity in the research populations (1). Geographic limitations also limit access for rural communities whose members have to travel great distances to access clinical research (5).

Diversity among research participants continues to lag behind community demographics, resulting in a lack of applicability for many community members. The homogeneity of research participants, whether by age, gender, race, ethnicity, or socioeconomic status, prevents the generalizability of findings and masks potential confounders. Partnered co-design of studies that

align with the health priorities of the communities most likely to benefit from study results remains the exception, not the norm. Models of bi-directional engagement between participants and researchers to inform study development and implementation in its earliest stages have proven successful, producing high levels of satisfaction amongst community members and investigators alike (6). Common successful approaches for recruiting underserved racial and ethnic groups include the involvement of community advisory boards to align study designs with community health priorities, collaborating with community-based organizations, and engaging in community-based locations (7). This suggests that building organizational and physical infrastructure to support community collaboration and foster trust-building relationships with a diverse group of community members can positively impact the engagement of diverse communities in research. Moreover, logistical and geographical barriers to participating in clinical research represent uniquely actionable factors. Here we describe one academic medical center's journey to creating a free-standing clinic dedicated to accessible research participation, education and training programs, and community engagement.

### **Establishing a Free-Standing Research Clinic Amid a Pandemic**

Duke Health, comprising the Duke University Health System (DUHS) and the Duke University Schools of Medicine (SOM) and Nursing (SON), has a large site-based clinical research program in Durham, North Carolina. There are 24 clinical research units that are the operating business units responsible for clinical trials and research studies. These units enrolled more than 29 400 participants in 2000 studies in the fiscal year 2024 and are primarily supported by a diverse portfolio of industry, state, foundation, and federal funding. While many studies are conducted in inpatient settings, others interact with research participants in central and outlying clinics, and occasionally in University-owned or leased administrative buildings.

To improve participant and researcher experiences for intensive phase I research studies, the SOM created a research-only space in the heart of its medical center dedicated to early-phase clinical trials. The Duke Early Phase Research Unit (DEPRU), established in 2008, includes a state-of-the-art clinical research confinement unit, dedicated 24/7 medical staff coverage, and a processing laboratory. This unit offers an effective model for a research-dedicated site. However, both its central location within the medical center complex and the higher costs required for managing high-risk early-phase clinical trials make the space less desirable for lower-risk studies and community research collaborations.

In the fall of 2019, following feedback from investigators across Duke, the SOM evaluated the need for off-site research space. At the conclusion of these discussions, several needs were identified: a research-dedicated outpatient space; a centralized, well-outfitted laboratory; investigational product infusion capability; a 65-foot by 5-foot area for mobility testing free of obstructions; secured cabinets and closets for equipment and study document storage; and offices for research staff. The SOM began searching for a facility to fulfill these needs with the key evaluation criteria of 1) proximity to Duke University Medical Center campus, 2) accessibility via public transportation and free on-site parking for participants, and 3) ease and affordability of remodeling to accommodate stated needs.

In March 2020, only a few months after completing the needs assessment, the COVID-19 pandemic created an urgency in the search for a research-dedicated space. As SARS-CoV-2 research needs rapidly expanded, clinical studies involving hospitalized patients with COVID-19 and studies for vaccinated participants opened. Safe spaces for follow-up study visits after discharge or post-exposure were urgently needed. Additionally, outpatient research areas large enough to accommodate healthy participants for COVID-19 vaccine trials were lacking. Neither the health system nor current research infrastructure, such as DEPRU, could accommodate such needs while continuing to serve vulnerable patients and participants. An opportunity manifested in an available for lease space previously used as an outpatient medical clinic in the Durham community. This two-story, 22 000-square-foot building offered 30 exam rooms with sinks, a laboratory space, plenty of onsite ground-level parking and immediate access to public transportation. Clinic renovations began in August 2020 to update information technology for compatibility with health system requirements. Duke Research at Pickett (R@P) officially opened on October 5, 2020, only 3 months after identifying the building. Vaccine studies began on premise one week later and investigational monoclonal antibody IV-infusion treatment studies began on-site within a month.

A core research staffing team was developed to support the clinic's research operations. As many non-essential studies were paused early in 2020, staff willing and able to work with participants with COVID-19 were hired to form a central research support team working from R@P and serving COVID-19 studies in hospitals, clinics, homes, and community centers. An intense hiring focus was placed on bilingual clinical research coordinators to support the large Latine communities in Durham and the surrounding areas that were significantly impacted by

COVID-19. Together with the R@P facility, the staffing team became a validated research service center (Core) in January 2021, serving investigators and studies across the research enterprise.

In July 2021, R@P expanded operations to accommodate research across all disease states and populations, including pediatrics and geriatrics, using 4 clinic zones to safely separate participant groups, including a zone that remained dedicated to COVID-19 studies and a zone dedicated to pediatric participants. Between 2021 and 2022 the service center broadened its services to support the gradual transition of screening visits for healthy volunteer studies and lower-risk study visits from DEPRU to the more accessible R@P. Meanwhile, a multicultural team of clinical research staff continued to expand to ultimately include >30 research, regulatory, and nurse coordinators, of whom up to 25% are bilingual in Spanish and English. To date, an overall portfolio of 78 studies across 13 clinical research units have been served at the R@P site (Table 1). A timeline depicting the milestones of this project is shown in Figure 1.

### **Community Engagement in Research and Events**

While the NIH impetus to support community-engaged research has continued to strengthen, a diverse group of representatives from community-based organizations in Durham noted neighborhood communal and clinical space dedicated to authentic health and research engagement was lacking. As the safety isolation needs of the COVID-19 pandemic decreased and with this community feedback in mind, R@P afforded a uniquely accessible location for community-engaged and partnered initiatives. In late 2020, a proposal was submitted to The Duke Endowment to support a re-imagining of R@P as a focal point for a cross-institutional program to pursue opportunities promoting equity and diversity in research. Leaders across multiple SOM divisions developed a grant proposal for the Research Equity and Diversity Initiative (READI) with the intent of using R@P as a facility from which to base community-engaged initiatives while continuing operations as an outpatient clinical research site. Additional READI goals included increasing diverse participation in clinical research, enhancing community-engaged research, and maximizing community-engagement outreach activities that promote awareness, education, and participation in clinical research among underserved and marginalized populations. The READI grant was awarded in June 2021 to leverage the current research infrastructure to meet its primary aim of creating a network of community facilities. The READI Community Advisory Council (CAC) were fully engaged partners in this work, each

bringing together their lived experiences, expertise, and unique perspectives to inform and provide recommendations to guide READI programming. The CAC is comprised of 19 members representing 15 community-based organizations including patients, faith leaders, community-based clinic providers, community-based healthcare organizations, and county service representatives.

### **Community-engaged Research Voucher Program**

In partnership with READI, R@P has served as the primary location for a community-engaged research voucher program, developed to fund investigator-initiated clinical research projects that incorporate community engagement principles including alignment with community health priorities and include partnerships with community organizations. READI vouchers included the use of the R@P facility and/or clinical research professional (CRP) staffing support for participant recruitment, statistical, and data management, all managed through the Duke Office of Clinical Research Service Center (Core). Three awards totaling \$195,000 to support 5 clinical research studies focusing on health conditions that disproportionately affect underserved populations in the Durham community were selected for funding.

### **Creating a Culturally Reflective Research Site**

Working from recommendations of the READI CAC, multiple improvements were made to the R@P facility to create welcoming spaces for community engagement and outreach. In 2023, READI supported the transformation of a large, minimally used training room into a vibrant community meeting room, which is available at no cost to community organizations. The community room includes audio-visual equipment and mobile tables and chairs to provide flexible seating arrangements. A mural depicting the greater Durham community and the importance of equity, diversity, and community engagement in clinical research was commissioned to adorn its walls (Figure 2). Volunteers from a variety of Durham communities were involved throughout the artistic process, from the selection of the artist and design development to the painting and installation of the mural. An event to unveil the mural brought together over 200 residents from the Durham community and surrounding areas, including researchers, local community-based organizations, youth, and others (8).

In the following 6 months, the space was used for community discussions of clinical research ethics, a celebration and recognition of students completing the Duke CTSA/Durham Technical Community College Clinical Research Equity Scholars program (9), and a career

pathway program for high school and undergraduate students focused on clinical research as a profession. Outdoor spaces have been furnished with tables and benches for use by visitors and research staff overlooking a pollinator garden and a Little Free Lending library installed by local Scouts from inaugural inclusive scout troops for two Eagle projects. Information about the space is continually disseminated to local partners and at community events with the goal of increasing usage of the space and, by extension, spreading awareness of the benefits of clinical research engagement.

### **Multiuse for Research Training/Education**

The advent of a well-configured, multi-purpose room within a designated research clinic space has afforded unique opportunities for training the current research workforce and engaging the next generation of clinical research professionals (CRPs). Even before the official launch of the READI community room, R@P was recognized as the ideal location for centrally provided education for CRPs and local students alike. Phlebotomy training, a required hands-on experience for all non-licensed CRPs who draw blood for research protocols, is available in this expansive space with room for several phlebotomy chairs and ready access to other materials and supplies. Large meetings and an institution-wide revalidation of Clinical Research Nurse Coordinators also leverage the facility. In addition to internal workforce training and education, R@P is ideal for interns and student learners, largely due to easy access, the variety of therapeutic areas and study types, and the large team of clinical research professionals. Local community colleges and Historically Black Colleges and Universities (HBCUs) have academic agreements with Duke to serve as an internship site for students in CRP programs. For the past 2 years, interns have had heightened exposure to a wide variety of research tasks across diverse therapeutic areas while interacting with the numerous CRP mentors who staff the research site. Moreover, because R@P and DEPRU are synergistic sites under the Duke Office of Clinical Research umbrella, interns also learn about research coordination and experience study visit activities that are unique to early-phase research, covering the entire translational spectrum from Phase 1 to Phase 4 clinical research and trials.

Importantly, the focus on ensuring ease of access that factored into making R@P a welcoming site for community members has likewise created an ideal space for engaging young learners in clinical research. A recent collaboration with the Duke Building Opportunities and Overtures in Science and Technology (BOOST) program brought a cohort of middle school



students into the clinic to interact with CRPs, learn about studies, and role-play clinical research activities in real research spaces. Through a new partnership with Durham Public Schools and Durham Technical Community College, work-based learning experiences including summer camps, symposia, CRP shadowing, and internships for high school students will be created. This marks an expansion of Duke's K-12 science, technology, engineering, and mathematics programming to include clinical research and provides early-career pathways from high school into clinical research professions.

### **Challenges Faced and Opportunities for Success**

Despite having addressed a great need within the institution and community, limitations to the current free-standing research site remain. The 22 000-square-foot building footprint was much larger than the original need for 9 clinic rooms. As a result, the facility is not fully utilized on a daily basis and yields considerable costs for leasing, utilities, maintenance, and cleaning. The original vision also included locating a research clinic accessible via personal automobile and public transportation. Although the site had previously been on a public transportation route, after signing the lease, it was discovered that the bus stop had been moved, leaving the closest access 0.5 miles away on a narrow-shouldered road without sidewalks. In an effort to overcome this challenge, patient transportation has been arranged on an as-needed basis. Efforts are ongoing to resume public transit services in the area. Furthermore, R@P, geographically located in a suburban area, is separated from the highest concentrations of community populations that have been traditionally underserved in health care and research.

A hurried timeline and limited real-estate options during the COVID-19 pandemic transformed the plan from finding the perfect location to a sufficient location that could meet most aspects of the original vision as well as structural needs. This continuing work seeks to address the remaining gaps by expanding a network of community-based locations for research as well as encouraging and supporting more community-immersed research. Ongoing projects will continue to enhance the infrastructure, such as further exploration of public transportation options to support the R@P location.

### **Conclusions and Future Directions**

Physical infrastructure to support the needs of clinical research in a community setting is essential, yet often overlooked, and lacks supportive funding. Clinical research sites located on large academic medical center campuses can be challenging for participants to access. Multi-

level parking garages leading to clinics dispersed down long corridors make it difficult for participants with mobility issues and parents with young children, among others, to reach. Clinic schedules are often inflexible to support research visits outside normal business hours.

Infrastructure development to support community-engaged research is just one piece of the solution to equity in research. Fiscal and administrative complexities at the institutional level can be difficult for community organizations to understand and navigate, producing partnership inequities in pre- and post-award periods (10). Moreover, diversifying the patient-facing CRP workforce is a known area for growth and has been tagged as an important part of reaffirming trust in diverse communities (11). Among CTSA consortium leaders, additional strategies to support community engagement in research included increased funding for health equity and community-engaged research, opportunities for research training to community members, and the hiring of research staff from within the community they will serve (12).

Today, the free-standing R@P clinical research site has demonstrated its utility not only for supporting the Duke clinical research enterprise, but more importantly for supporting research innovation holistically with community input and engagement. R@P has better accommodated participants with its flexible hours of operation, accessible parking, more culturally sensitive environment, and simplified layout. Moreover, community organizations have used this accessible space as a gathering place to collaborate on health, health equity, and research projects alongside staff, faculty, and students from a local HBCU and community college. Local students are engaged in on-site research-based training and education programs to explore potential career opportunities, thereby taking advantage of the experienced and multicultural team of research staff at the site. Sustaining the partnership with the READI CAC as trusted leaders for directing authentic community engagement will support the continued efforts of the facility as a primary conduit for communities to learn more about how research can improve population health dissemination and translation.

This inclusive, multipurpose facility intends to continue serving as a model for making clinical research accessible to the broader community while training current research staff and the next generation of CRPs. With the inputs of funding, technology, people, and space with R@P, progress is now being made on long-term goals to increase the diversity of research participants, foster community trust in health and research initiatives, and translate research findings into action amongst underserved, under-engaged, and under-represented populations.

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## References

1. Allison K, Patel D, Kaur R. Assessing multiple factors affecting minority participation in clinical trials: development of the Clinical Trials Participation Barriers Survey. *Cureus*. 2022; 14(4). doi:10.7759/cureus.24424
2. Clougherty JE, Kinnee EJ, Cardet JC, Mauger D, Bacharier L, Beigelman A, Blake KV, Cabana MD, Castro M, Chmiel JF, Covar R. Geography, generalisability, and susceptibility in clinical trials. *Lancet Respir Med*. 2021; 9(4):330-332. doi:10.1016%2FS2213-2600(21)00046-1
3. Institute of Medicine. *The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research*. The National Academies Press; 2013. Accessed May 15, 2024. <https://www.ncbi.nlm.nih.gov/books/NBK144067/>
4. Stallings SC, Cunningham-Erves J, Frazier C, Ichimura JS, Hurd TC, Jurinsky J, Acquaye A, Dalton JS, Wilkins CH. Development and validation of the perceptions of research trustworthiness scale to measure trust among minoritized racial and ethnic groups in biomedical research in the US. *JAMA Netw Open*. 2022; 5(12):e2248812. doi:10.1001/jamanetworkopen.2022.48812
5. Bharucha AE, Wi CI, Srinivasan SG, Choi H, Wheeler PH, Stavlund JR, Keller DA, Bailey KR, Juhn YJ. Participation of rural patients in clinical trials at a multisite academic medical center. *J Clin Transl Sci*. 2021; 5(1):e190. doi:10.1017/cts.2021.813
6. Emmons KM, Curry M, Lee RM, Pless A, Ramanadhan S, Trujillo C. Enabling community input to improve equity in and access to translational research: The Community Coalition for Equity in Research. *J Clin Transl Sci*. 2022; 6(1):e60. doi:10.1017/cts.2022.396
7. Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-engaged approaches for minority recruitment into clinical research: a scoping review of the literature. *Mayo Clin Proc*. 2021; 96(3):733-743. doi: 10.1016/j.mayocp.2020.03.028
8. Duke Clinical & Translational Science Institute (CTSI). Colorful Mural Highlights Duke's Commitment to Community-Engaged Research. July 12, 2023. Accessed May 15, 2024. <https://ctsi.duke.edu/news/colorful-mural-highlights-dukes-commitment-community-engaged-research>

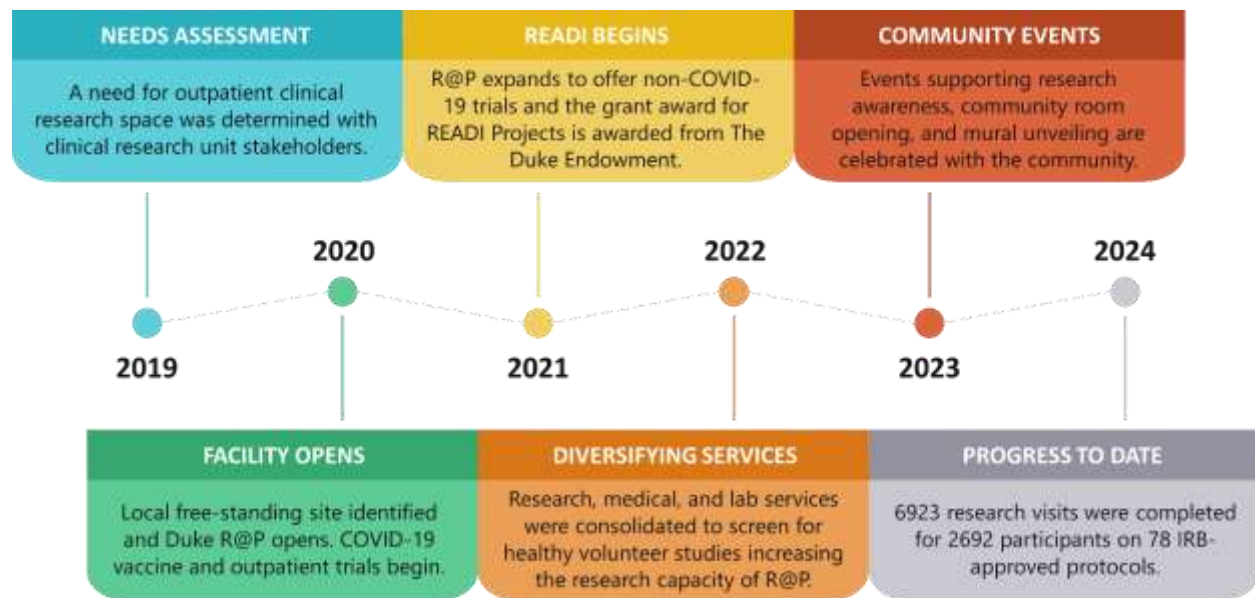
9. Duke Clinical & Translational Science Institute (CTSI). Equity Scholars Present Research Capstone Projects. October 17, 2023. Accessed May 15, 2024. <https://ctsi.duke.edu/news/equity-scholars-present-research-capstone-projects>
10. Carter-Edwards L, Grewe ME, Fair AM, Jenkins C, Ray NJ, Bilheimer A, Dave G, Nunez-Smith M, Richmond A, Wilkins CH. Recognizing cross-institutional fiscal and administrative barriers and facilitators to conducting community-engaged clinical and translational research. *Acad Med.* 2021; 96(4):558-567. doi: 10.1097/ACM.0000000000003893
11. Associate of Clinical Research Professionals (ACRP). NIH Affirms Importance of Diversity in Clinical Trial Workforce. October 19, 2021. Accessed September 25, 2024. <https://acrpnnet.org/2021/10/19/nih-affirms-importance-of-diversity-in-clinical-trial-workforce>
12. Boulware LE, Corbie G, Aguilar-Gaxiola S, Wilkins CH, Ruiz R, Vitale A, Egede LE. Combating structural inequities—diversity, equity, and inclusion in clinical and translational research. *N Engl J Med.* 2022; 386(3):201-203.

**Table 1.** Use of Pickett Road Clinic from January 2021-March 2024 by Clinical Research Units

	<b>n</b>	<b>%</b>
Research Protocols	78	
Clinical Research Unit		
Medicine	17	21.8%
Pediatrics	15	19.2%
DEPRU	10	12.8%
DHVI	9	11.5%
Anesthesiology	8	10.3%
Surgery	5	6.4%
Emergency Medicine	4	5.1%
CTSI	3	3.8%
Heart Center	2	2.6%
Oncology	2	2.6%
Population Health Sciences	1	1.3%
School of Nursing	1	1.3%
Orthopedic Surgery	1	1.3%

DEPRU = Duke Early Phase Research Unit; DHVI = Duke Human Vaccine Institute; CTSI = Clinical and Translational Science Institute

**Figure 1: Duke Research at Pickett Milestones by Year**



**Figure 2: Mural Painting and Engaging Local Students**



**Left:** Research faculty and staff paint the mural in the Research Equity and Diversity Initiative (READI) Community Room.

**Top right:** Local high school students are engaged to learn about clinical research professional roles supporting research.

**Bottom right:** The 34-foot-wide mural designed by Max Dowdle symbolizes the mission of READI while depicting the vibrant nature of the greater Durham community.