

Special Communication

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A qualitative evaluation of the Research Equity and Diversity Initiative's (READI) research support voucher program and its community engagement support

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Abstract

The Duke Research Equity and Diversity Initiative (READI) was established in 2021 to engage Durham and surrounding communities in clinical research and build capacity to promote equitable access to research participation. Within READI, a voucher program was launched with the goals of increasing diverse participation in clinical research, improving community-partnered research, and enhancing community engagement. The vouchers leveraged a stand-alone, community-centered, outpatient research clinic, the Duke Research at Pickett (R@P) facility, which was originally opened to support COVID-19 trials. A formative evaluation of the voucher program was conducted with 3 voucher-awarded teams, READI personnel, and R@P staff. Data included 18 semi-structured interviews ($n = 14$) over two timepoints (Spring 2023, 2024). A rapid response analysis approach was used. Data indicate that READI voucher-awarded services were useful for voucher teams, with value for supporting community-engaged efforts, making research participation accessible, creating a community-centered and streamlined service facility, and personnel development benefits. Communication and flexibility of support services facilitated program implementation. Challenges occurred in service utilization logistics and incorporating community engagement into research support services. Ultimately, we find that a research support program with embedded community engagement support is feasible; this type of support can be integral in normalizing community-engaged research.

Introduction

Diverse participation in clinical research is vital for scientific advancement and promotion of health equity [1–3]. Community engagement in research is comprised of effective strategies to improve translation of research findings to broad populations and has numerous societal benefits including addressing prevalent health issues [4–6]. Multiple strategies can support such engagement, including building community partnerships, sharing knowledge between researchers and communities, and creating supportive infrastructure and policies [7–10]. A service center model provides a unique opportunity to facilitate community-engaged research by embedding community engagement support directly within traditional research support services. This embedding has the potential to enhance and normalize community engagement as a best practice in clinical and translational research. A voucher program supporting service center use can facilitate access to these services, particularly for those who could or would not have otherwise engaged such support and could potentially inform researcher perspectives or knowledge on community engagement.

In 2020, the Duke University School of Medicine (SOM) launched the Duke Research at Pickett (R@P) facility, a free-standing clinical research facility in the Durham community that employs a service center model. In 2021, the Duke Endowment granted support for the Research Equity and Diversity Initiative (READI), an infrastructure initiative designed to engage the community, build capacity to promote equitable access to research participation, and enhance clinical research workforce diversity [11]. This funding directly supported the facility, and with the R@P facility and services, READI utilized vouchers to provide research support within a community-centered clinical research facility and to support community-partnered research. This paper examines the implementation of the READI voucher program from the perspective

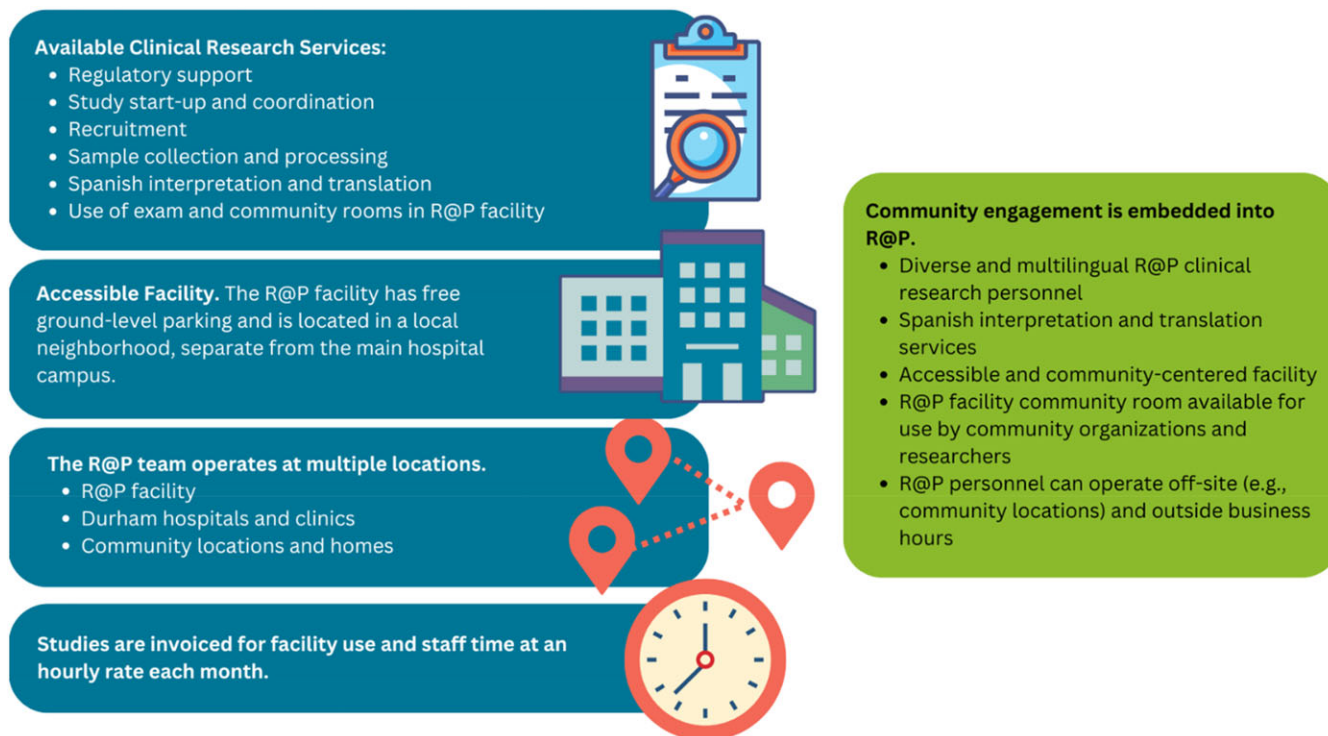


Figure 1. Research at Pickett service center key features. R@P = Research at Pickett.

of the voucher teams supported and those providing support. It describes the voucher program, the implementation of READI voucher support, and READI voucher benefits for involved parties.

Foundation: Voucher programs for service center use and Research at Pickett

Duke SOM offers over 70 service centers to support research. These service centers, operating as non-profit businesses, cover expenses such as wages, supplies, and equipment maintenance through user fees. In 2008, Duke launched its first voucher program under the National Institutes of Health Clinical and Translational Science Award (CTSA). Instead of awarding funding directly to an investigator, the program covered service center fees. This program encouraged investigators to engage with service center leadership, generate preliminary data, and utilize services effectively [12]. The Duke CTSA program allocated institutional funds to grant 28 vouchers totaling \$425k between 2008 and 2011. Due to its success, Duke SOM established its own voucher program in 2013, allowing researchers to seek funding from any of the SOM's service centers.

In 2020, the Duke Office of Clinical Research established the Research at Pickett facility, an easily accessible, community-centered outpatient facility staffed by a team of clinical research professionals for COVID-19 trials. The R@P facility and staff offer varied services (e.g., facility use, staff effort) for which individual studies are invoiced at an hourly rate, allowing for flexible staffing. In 2021, the Duke Endowment funded READI to enhance community health and health equity by fostering collaboration between community members and researchers [11]. READI leveraged the R@P facility and service resources, particularly in diverse recruitment, to further support community partnership. Hereafter, R@P collectively refers to both the facility and services,

which includes both on-site staffing and off-site staffing at research-related events. See Figure 1 for key features of R@P, including how a community-engaged orientation was embedded into R@P with READI. Further information on the development of R@P and READI is available in Van Althuis *et al* [13] and Taylor *et al* [14], respectively.

Duke Research Equity and Diversity Initiative voucher program

Inspired by the prior voucher program, READI staff proposed a similar model for R@P and launched a voucher program in 2022, funded by The Duke Endowment. The Request for Applications (see Supplement 1) called for projects aligned with community health priorities, with a preference for those that included community partners as part of the research team. Recipients of voucher funding were encouraged to utilize the R@P facility and services (see Figure 1) to increase diverse participation in clinical research, improve community-partnered research, and enhance community engagement. The READI voucher program also funded a data manager and statistician to support voucher studies. Additionally, the funding aimed to support outreach activities that raise awareness, educate, and increase diverse clinical research participation, particularly focusing on underserved racial and ethnic populations.

Funding was granted to three voucher teams, supporting five research projects (two teams had multiple projects) from July 2022 to June 2024. This award period began with onboarding processes. Projects concentrated on community-partnered research with an emphasis on fostering clinical research diversity and enhancing community health, targeting conditions that disproportionately impact underserved populations, including hypertension, chronic kidney disease, and keratoconus [15–18].

Table 1. Respondent breakdown

Respondent Group	Timepoint 1 (Spring 2023, 7 Interviews)	Timepoint 2 (Spring 2024, 11 Interviews)
READI Personnel	3	3
Voucher PIs	3	2
Voucher Team Members	1	1
R@P CRCs	0	5

Materials & methods

READI's evaluation team, led by trained doctorate-level evaluation professionals (PBM and JS), conducted a formative evaluation of the voucher program to examine the program's implementation and early outcomes, utilizing process and outcome evaluation approaches. Core evaluation questions included: (1) What are the experiences of READI personnel, R@P clinical research coordinators (CRCs), and voucher principal investigators (PIs) and team members in the provision or utilization of voucher-awarded clinical research services? and (2) What is the impact of voucher-awarded funding and services on voucher teams' ability to achieve READI goals?

To provide a close lens on process and context, qualitative data was collected via semi-structured interviews at two timepoints (Spring 2023, 2024; approximately 6- and 18-month post-onboarding) from four purposively selected groups: READI personnel involved in voucher-awarded service coordination, R@P CRCs assigned to the voucher studies, and voucher PIs and team members. Core evaluation questions informed the interview guides, and they were tailored by respondent group and voucher study (see Supplement 2 for interview guides). Distinct interview guides were developed for those providing services (READI personnel and R@P CRCs, with modifications within one guide for each) and those utilizing services (voucher PIs and voucher team members, with modifications within one guide for each).

Interviews averaged 38.3 min (range: 18.6–58.7 min; see Supplemental Table 1 for breakdown by group) and were recorded, via videoconferencing. Email invitations to participate were sent to all voucher team ($n = 9$) and READI personnel ($n = 3$) for both timepoints, while R@P CRCs ($n = 6$) were invited to the second timepoint so that they could provide perspective well after awarded studies began enrolling. Respondents were informed that their participation was optional and confidential. In total, JS and PBM conducted 18 interviews with 14 respondents (three READI personnel, four voucher PIs, two voucher team members, and five CRCs; see Table 1). All READI personnel and one PI agreed to be interviewed at both timepoints. One PI from each voucher team was interviewed in the first timepoint.

Respondent breakdown. READI: Research Equity and Diversity Initiative; PIs are principal investigators; R@P: Research at Pickett; CRCs: clinical research coordinators.

Similar to prior translational research conducted by PBM and JS, analytic methods were informed by rapid response analysis to quickly provide READI with findings that could inform ongoing processes [19,20]. First, PBM created timepoint-specific Excel workbook documents with a data table or sheet for each respondent group. In each data table, rows represent discussion topics organized by core evaluation question and columns represent each respondent (see Supplemental Table 2 for example).

Using interview notes, recordings, and transcripts, PBM paraphrased responses into these tables. PBM closely reviewed the data tables, comparing across respondent groups, and drafted initial themes in response to the core evaluation questions. SQ provided early feedback on initial themes. JS and PBM discussed, clarified, and then finalized themes. PBM and JS removed some descriptive information about respondents, such as specific roles and names, in the results whenever possible to ensure appropriate respect for respondents. Respondents reviewed identifiable findings, and provided feedback, before they were shared with non-evaluation team individuals. Adjustments were made to ensure comfort and confidentiality while retaining data accuracy. Four authors (NJB, SAF, LCS, and ST), who were engaged in the voucher program and READI overall, participated in this evaluation. However, access to interview data was restricted to the evaluation team (PBM, SQ, and JS) and author-respondents only had access to their own data. Evaluation protocol was deemed exempt by the Duke Health institutional review board. Reporting followed the Consolidated Criteria for Reporting Qualitative Research guidelines (see Supplemental Table 3 for checklist) [21].

Results

See Figure 2 for theme frequency.

Implementation processes & facilitators

Service utilization

Voucher teams were expected to, and did, utilize the R@P facility and CRCs (see Table 2). CRC tasks and facility use varied by study. READI-funded database management support was available outside of voucher-awarded services but only utilized by one team. After informal check-ins with teams, READI personnel coordinated the provision of additional services and support, such as a project manager to a team with early-career investigators.

Service flexibility

Onboarding voucher studies differed from the typical R@P process. Typically, investigators have a clinical research need, outline their needs in a meeting with R@P leadership, and then are told about R@P services. For the voucher program, PIs instead had an idea that received limited award funding, determined their needs, and then identified potentially required services. Onboarding experiences differed between voucher PIs who had prior R@P experience with typical service needs and those who did not. One team had a *clear plan for their needs, which they described as "typical,"* and the R@P team already worked with the PI which led to a relatively smooth process of onboarding. A second team had previously engaged with R@P services before the voucher, but their needs were not as directly within typical R@P services (e.g., they had community engagement tasks for CRCs outside of recruitment and study visits and wanted CRCs who best represented the communities with whom their team engaged). A *third team required services* not usually provided by R@P (e.g., study planning support) and also changed investigators during the award period; these factors slowed the start of R@P service utilization.

When voucher teams had needs outside of the intended services, R@P needed to consider paths to service flexibility. READI personnel spoke about navigating these needs and connecting teams to additional resources (e.g., institutional regulatory resources). R@P considered expanding services if it

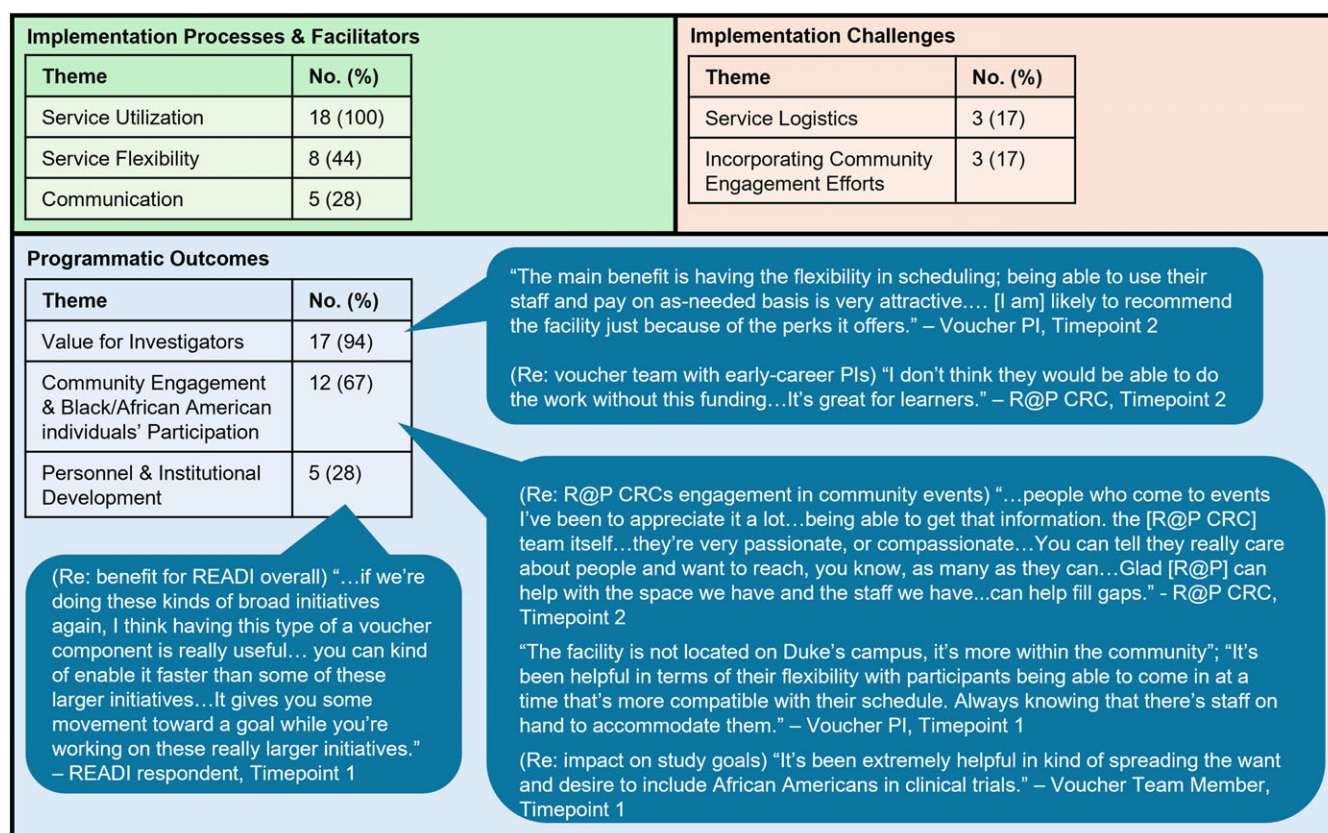


Figure 2. Theme frequency and programmatic outcome quotes. No. (%) of contributing interviews ($N = 18$). PI = principal investigators; R@P = Research at Pickett; CRCs = clinical research coordinators; READI = Research Equity and Diversity Initiative.

could serve multiple studies. Where in-house service expansion was not feasible, voucher teams were responsible for obtaining services elsewhere (e.g., genetic counseling). A PI indicated that not having all of their needs met through the voucher was challenging, though they appreciated READI personnel's willingness to discuss their concerns.

Communication

Communication among READI personnel, investigators, and CRCs helped resolve challenges related to differences in understanding study processes, study needs, and service utilization. For instance, a READI respondent shared that a voucher team expressed reluctance to use staffing services because they required flexible availability to accommodate participants. In a meeting, the PIs and READI personnel identified a mismatch in what the PIs thought was available and READI personnel's understanding of this team's service needs. They clarified needs and decided that R@P CRCs would be scheduled for set times and the voucher team would attempt to schedule participants for these times. If there were no participants, CRCs were directed to conduct other study tasks. This voucher team has shared that they have noticed an improvement in staffing availability over the past year.

Implementation challenges

Service logistics

The logistics of R@P service utilization also affected experience. At R@P, CRCs only bill for the time they are actively working on their assigned study. They are responsible for determining when they complete tasks outside of set study visits as they are assigned to

multiple studies. This provides teams with valuable staffing-service flexibility, a benefit of R@P services discussed in both timepoints. However, respondents shared that there were some challenging consequences. For instance, for CRCs assigned to approach pre-screened patients in a clinic before their appointment, delays or cancellations resulted in CRCs being in the clinic longer than anticipated. This made it difficult for CRCs to complete tasks in time set aside for other studies or be assigned to other studies, as their availability was somewhat dependent on the clinic's schedule. A CRC shared that while this study often required schedule changes, R@P studies are made feasible because multiple CRCs are assigned to conduct tasks when needed. A PI shared another issue related to R@P's billing practices, which was exacerbated by staffing turnover, a common challenge within the clinical research workforce. The time billed by CRCs depends on how efficiently they conduct study tasks. This PI noted that they were having trouble limiting staffing costs to what was feasible for their budget because CRCs were billing more hours than anticipated. This concern has been communicated to READI personnel and CRCs, and it has, in part, been addressed by careful budget and billing review.

Incorporating community engagement efforts

For community engagement efforts, voucher teams and R@P needed to consider established partnerships, between voucher teams and their community partners, as well as CRCs' training in community engagement practices. One team considered challenges in adding R@P CRCs to their outreach, particularly as they began the award period with established community partnerships

Table 2. Services and support received by voucher teams

Voucher Study Descriptions by Team	Expected Voucher-awarded Services and Support	Example CRC Tasks	Community Engagement Support	Additional Need-based Services and Support
On-site cohort-based behavioral intervention	R@P CRCs R@P facility use	Data collection Participant scheduling	Community-centered facility use for visits, including community partner-led sessions	R@P regulatory support
Genetic screenings at community events and on site; On-site randomized drug trial	R@P CRCs R@P facility use REDCap database manager	Recruitment via community event interactions Enrollment and data collection at community events and on site	Community-centered facility use for visits CRC availability to carry out tasks at community events	R@P regulatory support
Retrospective questionnaire; In-clinic device testing	R@P CRCs	Recruitment via phone calls Enrollment and data collection in clinic	CRC availability to carry out tasks at off-site clinic	R@P regulatory support R@P project manager Study planning support

Services and support received by voucher teams. R@P = Research at Pickett; CRCs = are clinical research coordinators.

and existing team capacity in community-engaged research. They also wanted to engage CRCs who best represented the communities with whom this team worked; this could be accommodated by R@P but initially limited available CRCs. There was an initial intent within READI to involve CRCs in their community engagement events. However, READI personnel shared that an external effort to conduct a community engagement training for Duke clinical research staff did not occur as planned; this, along with scheduling challenges, precluded R@P CRCs from being as involved in community engagement events as they would have liked. Despite these challenges, READI personnel reported that READI facilitated and practiced community-engaged work more frequently outside of the voucher program (e.g., hosting community events at the facility outside of the voucher program) compared to what occurred with the voucher teams (e.g., staffing community events for voucher teams).

Programmatic outcomes

Programmatic outcome quotes are provided in Figure 2.

Value for investigators

Respondents from each group supported the voucher program continuing after this cohort. Voucher PIs expressed interest in working with READI and R@P services again and would recommend them to other investigators; they highlighted several features. These include READI personnel's responsiveness to investigators' concerns, READI personnel's interest in studies' success, patient scheduling flexibility, the convenience of a multi-service facility, and competent staff that can be paid as needed. In addition, a READI respondent shared that READI voucher program success supports R@P by providing an opportunity to showcase its services.

Respondents believed that voucher-awarded services were useful for the teams, with specific benefits varying based on study stage and investigator experience. For a study led by early-career investigators, respondents reported that READI provided funding and services that may have been inaccessible otherwise. Additionally, this award provided a learning opportunity for these investigators, as READI personnel provided this team with broader guidance about research conduct. For other studies that were already underway and had more senior PIs, respondents from all

groups reported that capacity to conduct research was increased primarily through increasing research speed and efficiency. Indeed, a PI mentioned that while they could have conducted their study without R@P services, it would have been more difficult to do so and possibly more expensive as it likely would have required hiring full-time staff.

A voucher PI and team members from one study spoke to the unique and helpful staffing services they received via READI and the voucher beyond what they anticipated. This included useful survey feedback from their assigned R@P CRCs; a REDCap coordinator separately funded by READI, who helped them optimize their use of REDCap; and a READI intern who was not associated with the voucher, whom the team member described as attentive and helpful for community events, in-clinic work, and determining the utility of their survey data. Voucher team respondents from other studies discussed how R@P's ability to conduct research tasks made research participation feasible. For one study, CRCs called pre-screened participants before they were approached in-clinic for consenting and data collection prior to an appointment. This process gave them time to consider whether they wanted to participate. The PI of another study highlighted that they appreciated staffing availability as it allowed their study to flexibly schedule patients for research-related visits.

Community engagement & Black/African American individuals' participation

Despite challenges training R@P staff in community engagement, results also indicated benefits specific to community engagement efforts. One study with community-engaged processes already underway reported that the voucher program made it possible to augment staffing at their events, by streamlining the process for engaging participants at these events and flexibly accommodating participants who wanted to engage in the research from the R@P facility rather than the community events. Voucher team members and a CRC also highlighted that increased capacity to work at community events is beneficial for participants. They mentioned that community members appreciated learning about research and health issues and sharing what they learned with their loved ones.

Respondents described how the facility itself was beneficial for the voucher teams, including benefits for community partnership and engagement. Voucher team respondents reported that its

central location for the local community and accessibility (e.g., nearby parking) was preferable for their studies. One PI mentioned that since this location is separated from other Duke clinics, it provides a more comfortable environment for participants. Additionally, one team was able to host their community partner-led intervention sessions in a facility room. The centralization of many research services in one location (e.g., participant examinations, biospecimen collection and processing) allowed streamlined service experiences for both investigators and participants. PIs reported that this is uniquely valuable for participants compared to other similar facilities.

An initial voucher program goal was increasing research participant diversity. However, two voucher teams recruited from only one racial/ethnic group, Black/African American individuals. Yet, READI personnel reported that supporting these studies could result in an overall increase in research engagement at the R@P facility from this population. They suggested that by facilitating positive research experiences, those who have engaged with voucher-awarded services may be likely to participate in, and refer others to, R@P research. Indeed, a voucher team member reported that voucher-awarded services helped their team show African Americans that the clinical trials community wants to be inclusive.

Personnel & institutional development

There was evidence of the voucher program benefitting READI personnel, R@P CRCs, and READI overall. A READI respondent noted that working for READI and the voucher program has encouraged them to learn more about diversity and community-oriented research. Another READI respondent and a CRC shared that providing these services was beneficial for CRCs. They noted that CRCs enjoyed working on and learning more about patient/community-involved research studies and worked well with one another. A READI respondent also spoke about the utility of voucher programs as sub-initiatives within larger initiatives (e.g., READI) because they are actionable, their success is easy to ascertain, and they can be an early indicator of larger initiative success.

Discussion

These evaluation findings indicate that READI's voucher program and R@P supported voucher teams in making progress toward goals. Data indicate that READI voucher-awarded services and support were useful for teams, with respondents highlighting support for community-engaged efforts, accessible research participation, the value of a streamlined community-centered service facility, and benefits for personnel and READI overall. While there were challenges in service utilization logistics and embedding community engagement into research support, we found that communication and support flexibility facilitated implementation. These findings align with previous literature regarding the value of supporting community-engaged research efforts for clinical research and research participants [5,6].

They further suggest that embedding community engagement within research support services all at one site is feasible and beneficial for research teams, clinical research personnel, and their participants. This integration can support boundary-crossing partnerships among researchers and communities by helping normalize and institutionalize community engagement as an integral part of the clinical and translational research process [6,22]. Additionally, engaging in a voucher program may

reduce barriers to entry into community-engaged work and offer learning opportunities for early-career investigators.

However, there were challenges related to considerations of how research interacts with communities, including where R@P could not fully provide desired support. Key factors in enabling effective community engagement support include hiring staff that better fulfill related needs (e.g., more specific experience), co-designing community engagement training for clinical research staff with institutional community engagement resources, and intentionally incorporating this training alongside other clinical research staff training.

Two of the awarded voucher teams recruited only Black/African American individuals. Our evaluation suggests that successfully supporting these specific-population studies can be an important step toward achieving increased research participant diversity across various sociodemographic groups. Respondents spoke to the potential of increased future participation among Black/African American individuals because of the work done over the course of this award. While this project did not increase research participant diversity, it provided other forms of support for advancing research participation and positive research experience among those historically underserved.

Our evaluation suggests that voucher programs are valuable for service centers. Recovering costs solely through user fees can be challenging. Users often rely on grant funding to utilize their resources, which can result in delays in incorporating service center costs into grant applications or adjusting existing budgets. When there are limited users, the necessary fees for service centers to break even may be too high, posing affordability issues for investigators. This also may lead to underutilization of services as efforts are made to increase the user base. Our findings show that voucher programs provide an opportunity to demonstrate the utility and benefits of service centers for investigators who may not have approached them without funding, which may encourage future service center use. Future voucher programs should be flexible as applicants for these vouchers may have needs that are not well fit for intended service utilization. This is especially important for new service centers, or those engaging in novel services.

There are limitations to this evaluation. One set of voucher team PIs did not participate in the second timepoint of data collection. Thus, there is a missing perspective that could have affected the findings, such as including a team-specific implementation challenge. Additionally, voucher study participants were not included in this evaluation. Although separate work addressed voucher study participants' perspectives directly, our findings regarding participant benefits should be understood as an indirect perspective on the impact of voucher-awarded R@P services on participants. We also did not follow up with respondents after the funding period, which precluded assessment of any long-term voucher program effects. Future efforts should ensure data collection from as many respondent types as feasible and consider post-voucher program data collection to determine long-term effects. Finally, this study speaks to three voucher teams' experiences with one voucher program and site. Results may vary with other voucher programs or teams. Additional research on voucher programs that support community-engaged research would help determine further commonalities and differences, especially if designed to allow for comparisons with and without research support services.

Embedding community engagement support into traditional research support is a potentially integral, but not the only, step in

normalizing community-engaged and -partnered research and improving clinical and translational research. To further support authentic community engagement beyond facilitating access to relevant university personnel/facility resources, future voucher programs could be augmented to also include compensation for community partners engaged with research teams. In addition, future efforts should consider ensuring a research facility's site accessibility. Our data suggests that the R@P facility itself was beneficial and accessible to participants. However, we do acknowledge that there are further site accessibility needs that should be addressed ongoing, such as adding a public bus stop or considering additional research facilities in locations that are accessible to the various communities that Duke serves [13,14].

In conclusion, these evaluation data demonstrate that embedding community engagement support into traditional research support is feasible, beneficial for researchers and research personnel, and appears to improve research participation experiences in a community setting. Providing these services through a voucher program is likely a viable way to increase utilization of innovative service centers, reflecting the translational science principle of creativity and innovation [22]. Although this voucher program ceased with READI funding in 2024, these evaluation findings will inform R@P services as applicable. Future voucher efforts should consider flexibility in service provision, especially as it relates to varying investigator needs. Ongoing evaluation research is needed to further understand related voucher and service center experiences and impacts.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/cts.2025.10140>.

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