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Building research capacity at FQHCs: A model of support from the *All of Us* Research Program

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Abstract

The *All of Us* Research Program is an historic effort to gather data over 10+ years from one million or more people living in the United States to accelerate research and advance precision medicine. There is a particular focus on populations historically underrepresented in biomedical research who are often served by Federally Qualified Health Centers (FQHCs). However, FQHCs face significant challenges in participating in research. This paper addresses three common barriers faced by FQHCs and describes a management model that was used to support a group of FQHCs participating in the *All of Us* Research Program. Specifically, the paper addresses the challenges of building FQHC research capacity to operationalize and manage research activities, transforming and sharing Electronic Health Records and other data, and recruiting and retaining research participants. The central coordination management model, which was used to support the FQHCs, is a generalizable framework and can serve as an exemplar of how to engage FQHCs in other longitudinal research efforts. To date, the FQHCs have enrolled more than 10,000 participants in the *All of Us* Research Program. Their success is an indicator that with the proper support, FQHCs can successfully implement a complex biomedical research program in the context of their health centers.

Introduction

Barriers to minority research participation are well documented in the scientific literature and include mistrust, fear, cultural and linguistic differences, and logistical issues like childcare, scheduling conflicts, and transportation [1,2]. Where race and ethnicity are concerned, although African Americans and Hispanics represent 12 and 16% of the U.S. population, respectively, only 5% of clinical trial participants are African American, and 1% of participants are Hispanic [3].

Born out of the recognition that not all have benefited equally from clinical research, the *All of Us* Research Program [4], funded by the National Institutes of Health (NIH), emerged from President Obama's Precision Medicine Initiative [5]. The *All of Us* Research Program (*All of Us* or program) is a longitudinal data collection with an aim of recruiting one million or more U.S.-based volunteers who reflect the country's diversity. Multiple data types, including surveys, Electronic Health Records (EHRs), and biospecimens, are being collected from these volunteers. The program is poised to become the largest, most diverse U.S.-based longitudinal data collection. It aspires to glean critical insights into the diagnosis, prevention, and treatment of diseases, social determinants, environmental health risks, and the development of resources to transfer scientific knowledge into public health strategies—all with the aim of improving the health of the nation [6].

Diversity is a core tenet of the program, with a special recruitment focus on populations that have been historically underrepresented in biomedical research; notably, this includes racial and ethnic minorities as well as several other diversity categories. The program has identified nine categories as being historically underrepresented in biomedical research (UBR) [7]. They are listed in Table 1.

The *All of Us* Research Program relies on direct volunteers as well as multiple healthcare organizations including Federally Qualified Health Centers (FQHCs) to achieve its recruitment and retention goals. FQHCs provide healthcare services to many of the same UBR populations [8] prioritized by *All of Us*, however, significant barriers preclude widespread FQHC participation in research studies.

In 2011 and 2012, FQHCs from across the United States were surveyed about their experience with research. From the 386 respondents, some of the most frequently reported barriers were dedicated staff time to do research (87%), concerns about loss of productivity or income (80%), funding opportunities (72%), lack of training in applying for and conducting research (72%), data analysis (60%), and the ability to recruit and retain research participants (56%). Additionally, FQHCs with no prior research experience reported higher percentages of nearly all of these barriers [9]. Although studies have been completed at the state level [10,11], a review of the extant literature suggests that Beeson et al. (2014) is the only nationwide

Table 1. All of Us Research Program underrepresented in biomedical research (UBR) categories

Diversity category	Description of underrepresented in biomedical research
Race and ethnicity	Individuals who identify as other than White and non-Hispanic (i.e., Asian; Black, African or African American; Hispanic, Spanish, or Latino; Native Hawaiian or Pacific Islander; Middle Eastern or North African)
Access to care	Individuals who have not had a needed medical visit in the past 12 months or cannot easily obtain or pay for medical care as needed
Age	Children 17 or younger and adults 65 or older
Annual household income	Individuals with household incomes equal to or below 200% of the Federal Poverty Level
Disability	Individuals with either a physical or cognitive disability
Educational attainment	Individuals with less than a high school degree or equivalent
Sexual and gender minorities	Individuals who identify as gender variant, nonbinary, transgender, or something else. Individuals who identify as sexual, bisexual, gay or lesbian, or something else
Geography	Individuals who reside in rural and nonmetropolitan areas
Sex assigned at birth	Individuals who are neither male nor female (i.e., intersex)

exploration of barriers to community health center participation in research. This is notable because addressing these challenges is critical to further extending research opportunities to communities that have been historically underrepresented.

In 2016, NIH contracted the Centers for Medicare and Medicaid Services Alliance to Modernize Healthcare Federally Funded Research and Development Center (Health FFRDC) to support the *All of Us* Research Program. The Health FFRDC, which is operated by the MITRE Corporation, was tasked with running a pilot to determine whether FQHC participation in the *All of Us* Research Program would be feasible. After an initial start-up period that included developing protocols and workflows and testing enrollment strategies, the pilot was deemed successful, and MITRE transformed its pilot project infrastructure into an operational unit dubbed “Central Coordination” to support the FQHCs in a more long-term partnership with the *All of Us* Research Program. This management approach aims to support FQHC maturation and capacity building in research, ensuring they can independently and successfully engage, enroll, and retain participants in the program. To date, the eight FQHCs under the Central Coordination umbrella have successfully enrolled more than 10,000 participants (Fig. 1).

This paper describes three major challenges the FQHCs faced in implementing and executing the *All of Us* Research Program and how Central Coordination support helped the health centers to navigate them. The challenges and management strategies discussed in this paper align with many themes identified by Beeson et al. (2014), including FQHCs’ capacity to operationalize and manage research activities, transform and share EHR data, and recruit and retain research participants (Table 2).

Main text

FQHCs are community-based organizations that are partially funded with federal dollars and provide primary care in medically underserved areas. Presently, over 1,400 FQHCs operate in more than 14,000 medically underserved communities across the United States, providing primary care services for over 29 million people, including nine million children [12]. These centers provide care for any individual or family, regardless of their ability to pay, with a sliding fee scale applied for low-income patients. Of patients, 81% are publicly insured or uninsured [13], 91% are low-income, and 67% are members of racial and ethnic minority groups [12]. Individuals and families served by these health centers are among the most economically vulnerable in the nation and often have multifaceted health and social challenges.

Challenge 1: FQHC’s capacity to operationalize and manage research activities

The capacity to manage and operate a biomedical research program is critical to the success of a data collection effort like the *All of Us* Research Program. Prior research shows that only about half (56%) of FQHCs have ever conducted or participated in research, while 58% of those that have not participated in research are interested in doing so [9]. However, community health center participation in research faces a number of obstacles, including competing institutional priorities, lack of dedicated staff time and funding, and the need for research training and specialized skills like data analysis [9].

Challenge 1: Response strategies

MITRE set out to develop an infrastructure that would support the FQHCs to implement the *All of Us* Research Program locally, while building enduring capacity to become more autonomous within the program and, importantly, to seek additional opportunities to participate in or lead research independently. The infrastructure model and team, dubbed “Central Coordination,” comprises four work streams staffed with subject matter experts committed to bolstering FQHC success (Fig. 2).

Efforts to build research capacity locally have focused on strengthening research project management and administration expertise, including developing strategic and operational plans, drafting standard operating procedures and Institutional Review Board protocols, performing and incorporating data analysis, and generating and sustaining buy-in from local leadership and staff. Along the way, some enduring resources and practices have been generated; for example, to promote cross-FQHC collaboration and avoid duplication of efforts, Central Coordination hosts weekly calls where health center staff share lessons learned and best practices, offer support, and ask questions of each other.

Additionally, Central Coordination has promoted FQHC front-line research staff knowledge development to support specific program enhancements. One example is the recent commencement of returning *All of Us* Research Program recreational and health-related genomic results to participants [14]. The FQHCs aimed to prepare their front-line staff with fundamental knowledge of genomics and how genomics results would be shared by the program. Central Coordination supported the FQHC teams to form a working group, identify the needs of their specific communities, and implement a collaborative and methodical process to select and develop genomics resources for staff. The

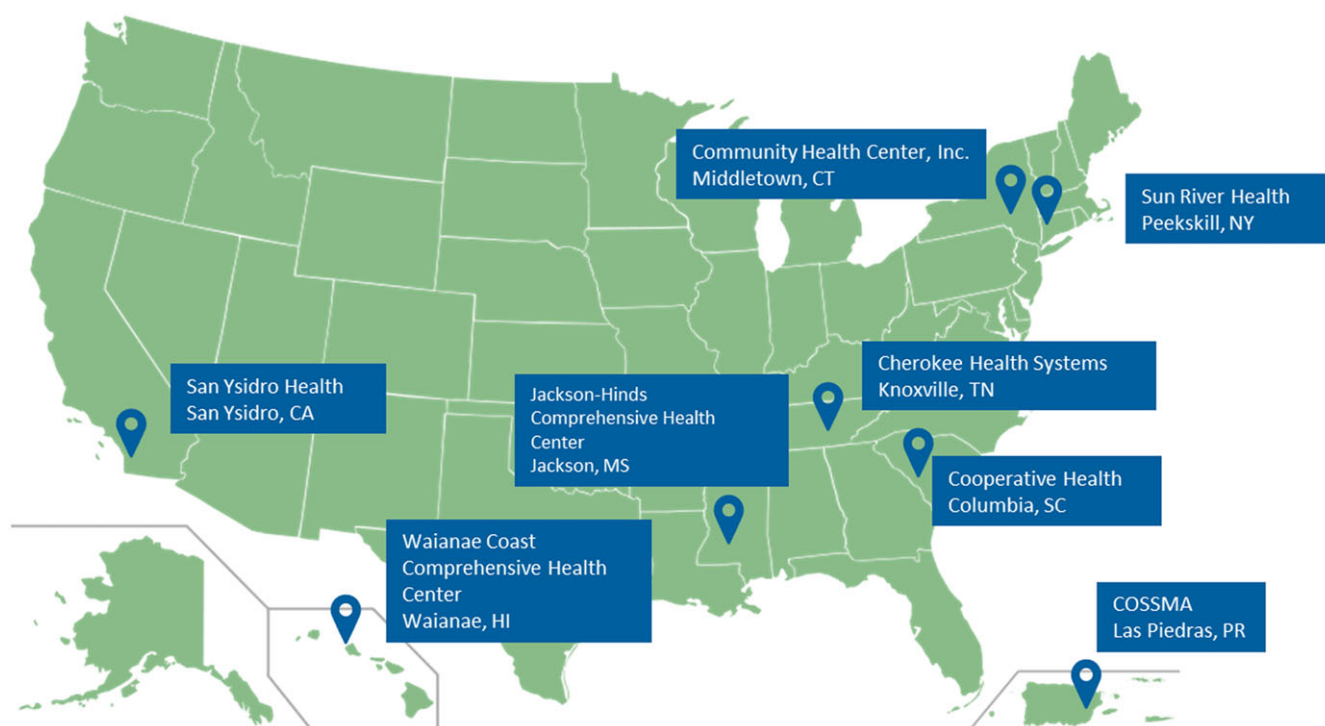


Figure 1. Federally Qualified Health Centers (FQHCs) supported by Central Coordination in the *All of Us* Research Program.

resources developed included a repository of job aids and other tools and a set of training to educate staff on terminology as well as equip them to answer potential questions from participants. To promote sustainability, Central Coordination partnered with the FQHCs to design “train the trainer” sessions, which built capacity for health center staff locally to implement learning opportunities that increased the self-efficacy of their teams to address genomics-related questions from participants. With the support of Central Coordination, the FQHC working group provided training in foundational genomics material to over 50 FQHC staff (approximately half of all FQHC personnel), trained 14 FQHC staff to become trainers, and created over two dozen resources. Later, some FQHCs created additional resources in Spanish.

Challenge 2: FQHC capacity to transform and share EHR data

Participants in the *All of Us* Research Program have the option to authorize a health center to share data from their EHR with the program [15]. To support the program’s requirements for sharing EHRs, each FQHC is responsible for identifying a consented participant’s record, extracting the data, transforming the participant’s data into the Observational Medical Outcomes Partnership (OMOP) common data model, and then loading the deidentified data into the Data Research Center for use by researchers. Aligned with findings from Beeson et al. (2014) [9], this component of the program presented challenges to community health centers, some of which were unfamiliar with accessing and manipulating data from their EHR systems, particularly for sharing externally. Even among the FQHCs participating in *All of Us* that had established research programs, some did not have staff with the required data analytic skills, or familiarity with analysis software like R or Python, making it difficult to initially improve their OMOP quality, which is critical to the program’s success.

Challenge 2: Response strategies

In light of these factors, Central Coordination customized support to meet each FQHC’s unique data management needs. For example, some FQHCs had no access to their EHR data other than preformatted reports, making an extract, transform, load (ETL) process nearly impossible. Central Coordination met weekly with these FQHCs, first to aid in the hiring of appropriately skilled staff, then to assist in gaining access to their full EHR database, and to provide guidance to the FQHC as it set up its ETL process. In some cases, the FQHC already had access to its EHR data and had experience with conducting research, so Central Coordination was needed only to provide R and Python coding support to aid in executing the *All of Us* protocols. Each FQHC now has dedicated and trained staff to perform its OMOP ETL, and all FQHCs have consistently met the quarterly upload schedule set by the program. The percentage of FQHC participants with EHR data flowing to the program is among the highest of any enrollment site, and FQHCs consistently perform well according to the program’s data quality metrics.

Challenge 3: FQHC’s capacity to recruit and retain research participants

Beeson et al. (2014) identified a concern about the ability to recruit and retain research subjects among 75% of community health centers that had not previously participated in research, and among 41% of those with research experience [9]. Many factors may contribute to this concern, not the least of which is the capacity of staff to strategically plan and execute the research program aligned with the attitudes, beliefs, and expectations of their communities. Indeed, when FQHCs began planning how they would implement the *All of Us* Research Program, it was unknown how their patients would respond to the program—for example,

Table 2. Federally Qualified Health Center (FQHC) challenges and Central Coordination support strategies

Barriers identified by Beeson et al. (2014)	Challenges experienced by FQHCs in the All of Us Research Program	Response strategies facilitated by Central Coordination Management Model
<ul style="list-style-type: none"> Dedicated staff time to conduct or participate in research An understanding about what is involved to conduct research 	Challenge 1: FQHC capacity to operationalize and manage research activities	<ul style="list-style-type: none"> Partnership with experienced Central Coordination and other All of Us Research Program staff Support for administering a research program (e.g., development of standard operating procedures, facilitation of Institutional Review Board requirements) Collaboration efforts, including sharing best practices and lessons learned
<ul style="list-style-type: none"> Data collection infrastructure 	Challenge 2: FQHC capacity to transform and share Electronic Health Record (EHR) data	<ul style="list-style-type: none"> Hiring appropriately skilled staff Coaching on data management software and skills Liaising with other All of Us data partners
<ul style="list-style-type: none"> Ability to recruit and retain research participants Data analysis Training in conducting research 	Challenge 3: FQHC capacity to recruit and retain research participants	<ul style="list-style-type: none"> Development of common dataset for monitoring Promoting individual and team professional development Providing infrastructure for process improvements and innovation

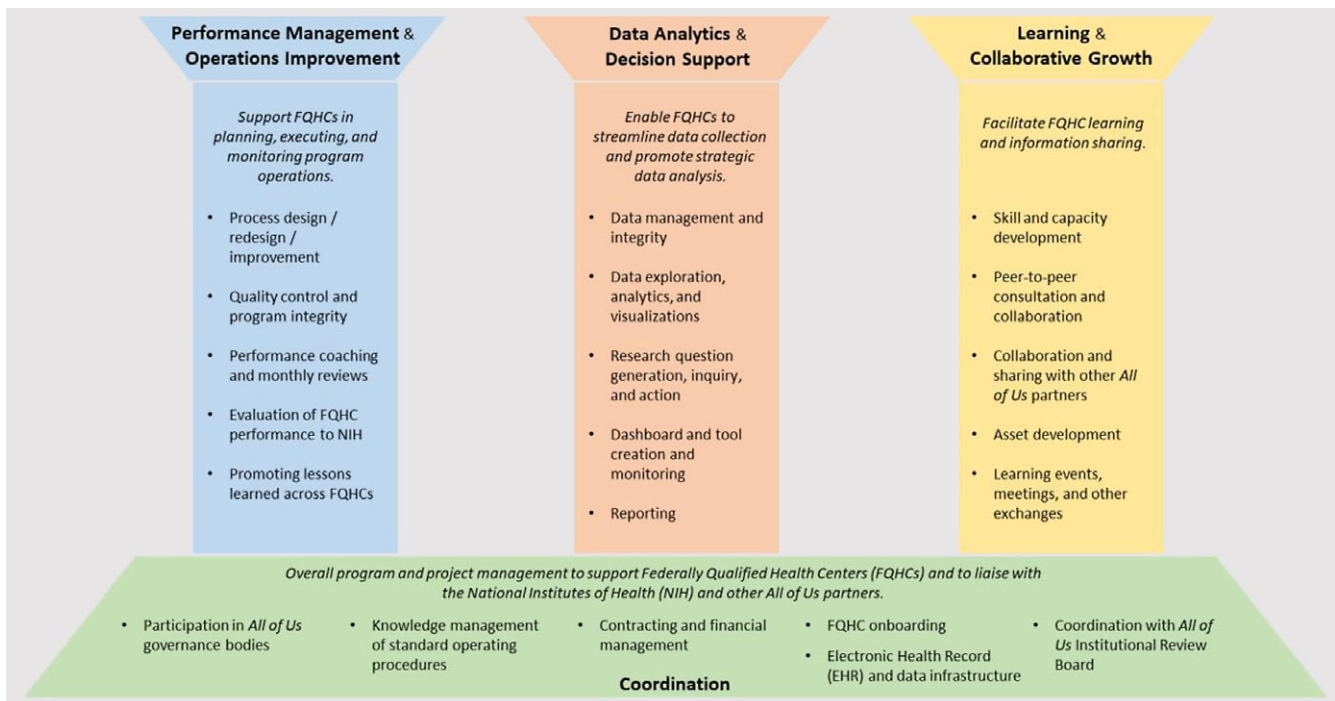


Figure 2. Central Coordination operational pillars.

what would be the potential motivators and barriers to joining. Moreover, there was not a uniform approach to monitoring engagement and enrollment-related operational data, such as how long each step of the program takes to complete. FQHCs and the Central Coordination team believed that having these data available would facilitate planning of engagement and enrollment approaches that were aligned to the needs of the community.

Challenge 3: Response strategies

First, to equip the FQHCs with data to plan operations, the Central Coordination team convened health center staff to plan an approach that would leverage the collective efforts of the FQHCs by pooling a common set of operational data, which became known as the FQHCs’ “common metrics.” Central Coordination

facilitated deliberations about what metrics to include and synthesized FQHC input to develop an instrument and protocol, which was ultimately approved by the program’s Institutional Review Board. As the “hub” entity serving several FQHC “spokes,” Central Coordination also established the processes for the health centers to transmit the common metrics data and took the lead in regularly synthesizing and summarizing the data into actionable findings to support the FQHCs’ recruitment, enrollment, and retention strategies. For example, when transportation was identified as a barrier for some patients, FQHCs implemented a variety of strategies to address this, which included not only arranging transportation in some cases but also using alternative enrollment locations.

Along these lines, NIH and Central Coordination have laid the foundation for and encouraged FQHCs to think about new and

different approaches to engagement and enrollment that could expand opportunities to join the program. As an example, recently several FQHCs expressed interest in a new enrollment stream, community members who are not FQHC patients (prior to this, FQHCs focused only on enrolling their patients). Central Coordination provided project management and facilitation support for a “pilot” of this approach, during which the FQHCs each developed and prototyped tailored processes and workflow amendments necessary to enroll non-patients at their respective clinics. The pilot included the collection of quantitative and qualitative data that health centers used to help inform their future non-patient recruitment and enrollment strategies. On multiple similar occasions, the FQHCs have used the nimble size of their *All of Us* teams and their diverse skill sets to innovate quickly and share insights with each other and the broader program consortium.

Conclusion

As the program has grown over time, the FQHCs have made the importance of their participation in the *All of Us* Research Program clear. The FQHCs serve populations that are essential to include in biomedical research to collect data and enable investigations that are representative of the diversity of the United States. Given the challenges many FQHCs face in identifying, pursuing, and sustaining research opportunities on their own, this model of Central Coordination support and collaboration between NIH, Central Coordination, and the FQHCs demonstrates that a proactive partnership and advocacy can support FQHCs’ success in future research. Purposeful partnership with FQHCs, in terms of financial and operational resources, will support FQHCs to include their diverse teams and communities in future research programs and will have lasting impact as it diversifies the pipeline of clinical and translational scientists and researchers. Moreover, we posit that the Central Coordination framework has utility beyond FQHCs, to support other organizations that are interested in and could add value to research, but perhaps lack the robust infrastructure or experience to effectively participate in research endeavors. For example, elements of the model described in this paper could be applied to supporting other types of community health centers (e.g., tribal and urban Indian health centers, FQHC “look-alikes”), minority-serving institutions (e.g., historically black colleges and universities), community- and faith-based organizations, and other entities that can offer the opportunity to participate in research to communities that have historically been overlooked.

Today, the FQHCs lead the *All of Us* consortium with innovative approaches to recruitment, enrollment, and retention, particularly of populations underrepresented in biomedical research. To date, the FQHCs have enrolled more than 10,000 participants in the program, with 95% of those participants being UBR. Looking ahead, the FQHCs will undoubtedly identify and be presented with new opportunities to innovate on behalf of *All of Us*, including in forthcoming program enhancements like pediatric enrollment and contribution of new data types. Furthermore, the FQHC teams are now positioned to conduct their own research using the data set created by the *All of Us* Research Program, (the “Researcher Workbench”), to which their participants have contributed. Beyond *All of Us*, the FQHCs’ growth in the program has set them up for successful participation in future research and serves as an indicator that other FQHCs can do the same.

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