

Best Practices for Participant and Stakeholder Engagement in the All of Us Research Program

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Preface

The All of Us Research Program (AoURP), a key component of the Precision Medicine Initiative launched by President Barack Obama in January 2015, is an ambitious and innovative research initiative led by the National Institutes of Health (NIH) with a mission to “revolutionize how we improve health and treat disease.”¹ The AoURP is collecting survey data, electronic health records, physical measurements, and biospecimens to build a large and diverse data set for health research. The program’s goal is to engage one million or more individuals living in the United States from diverse social, racial/ethnic, geographic, and economic backgrounds, as well as from all age groups over 18, regardless of health status. The expectation is that participants will remain involved with the AoURP for at least ten years, and perhaps even longer.

In response to a request from AoURP leadership, RAND researchers conducted a mixed-methods study of participant and stakeholder engagement in the AoURP to define a set of best practices that all participating regional medical centers (RMCs) involved in engagement activities should consider adapting at their sites before the national AoURP launch in May 2018. Engagement in the AoURP comprises the tasks of making potential participants aware of the AoURP, enrolling them to participate, and retaining them within the program. To develop best practices, we used the Rapid Assessment Procedure, which enabled us to combine information from several data sources, verify emerging findings through triangulation, iterate between data collection and analysis activities, and inform relevant stakeholders of emerging findings in a timely manner.

These findings should be of interest not only to RMC engagement leads and staff and AoURP leadership, but also to those interested in participant engagement and enrollment in the context of large and complex health studies.

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Summary

The All of Us Research Program

The All of Us Research Program (AoURP), a key component of the Precision Medicine Initiative launched by President Barack Obama in January 2015, is an ambitious and innovative research initiative led by the National Institutes of Health with a mission to revolutionize how health research is conducted.¹ Precision medicine is an approach to medicine that focuses on prevention and treatment strategies that take individual variability in genes, environment, and lifestyle into account.² To advance precision medicine, the AoURP is collecting survey data, electronic health records (EHRs), physical measurements, and biospecimens to build a large and diverse data set for health research. The program's goal is to engage one million or more individuals living in the United States from diverse social, racial/ethnic, geographic, and economic backgrounds, as well as from all age groups over 18, regardless of health status. The expectation is that participants will remain involved with the AoURP for at least ten years, and perhaps even longer.

Interested participants can enroll in the AoURP either (1) as direct volunteers through the AoURP website or the smartphone app or (2) at a participating health care provider organization (HPO) that is affiliated with one of the regional medical centers (RMCs), federally qualified health centers (FQHCs), or Veterans Affairs Healthcare Centers. The All of Us Journey, a 45-foot mobile educational unit that provides information about precision medicine and the AoURP, has been traveling across states to engage potential participants who do not live near one of the participating HPOs. This report focuses only on participant engagement that takes place at participating RMCs.

To become a full AoURP participant, individuals must have an EHR at one of the RMCs (or provide consent for the future use of their EHR if they ever obtain one); complete an online consent process; provide comprehensive information about their health, including survey data and physical measurements; and provide blood and urine samples.

In response to a request from AoURP leadership, RAND researchers conducted a mixed-methods study of participant and stakeholder engagement in the AoURP to define a set of best practices that all RMCs should consider adapting at their sites before the national AoURP launch in May 2018. According to the AoURP Operational Protocol, *engagement* refers to “the broad range of interactions between the program, people, and awardees and other organizations” (p. 61).³

The concept of engagement in the AoURP is about partnering with different stakeholders for the purposes of making potential participants aware of the AoURP, enrolling them to participate, and retaining them within the program. To develop best practices, we used the Rapid Assessment

Procedure (RAP), which enabled us to combine information from several data sources, verify emerging findings through triangulation, iterate between data collection and analysis activities, and inform relevant stakeholders of emerging findings in a timely manner.

Defining Best Practices, Strategies, and Tactics

A *best practice* is an effective, standardized way of achieving goals or delivering results that can work in a range of settings. To understand how RMCs are pursuing the goals of engagement, we distinguished between strategies and tactics. *Strategies* are plans that RMCs use to achieve a particular facet of the overall goal of engagement; *tactics* are the various steps taken to implement a strategy tailored to fit a local RMC or site. Because of the uniqueness of different RMCs and their sites in terms of the populations they serve, the amount of resources they have, and their previous experiences with research participation, we identify best practices at the strategy level rather than the tactic level. We consider a strategy to be a best practice if it was implemented by more than one RMC site, was deemed effective by one or more RMCs, and was mentioned as being effective in relevant literature that we reviewed. Given this definition, many best practices include tried and true approaches to engagement. Nonetheless, a lot of innovation takes place at the tactic level.

In addition to describing how RMCs engage participants and communities and stating whether a given strategy met our criteria for best practices, we provide a list of recommended best practices that all RMCs should consider. We also list some examples of possible tactics for each recommended best practice that RMCs might want to explore.

In this report, we discuss strategies and tactics associated with six facets of engaging both participants and relevant stakeholders (e.g., community leaders, RMC champions):

1. **Laying the foundation:** ways to work with communities to develop culturally appropriate engagement approaches and making potential participants aware of the AoURP
2. **Leading by example:** ways to build internal and external support for the AoURP that help RMCs prepare for participant enrollment
3. **Capitalizing on health care infrastructure:** ways to facilitate enrollment in health care facilities
4. **Tailoring and personalizing communications:** ways to deliver the AoURP message to potential participants and to engage them in the program over a long period of time
5. **Building and nurturing engagement teams:** ways to identify the right engagement staff and to organize and manage engagement teams
6. **Dealing with uncertainties:** ways to handle different questions that potential participants may ask during engagement activities.

In discussing engagement strategies and tactics pertinent to each facet of engagement, we identify possible unintended consequences that might be associated with use of these practices and explain what metrics might be employed to track the use of these strategies and tactics.

Finally, we propose a novel conceptual model for evaluating engagement success, which we call *the three Ms of engagement*. This model helps link key aspects of engagement: **metrics** (counts and descriptions of what was done to engage), **markers** (outcomes or benefits that engagement in the AoURP may bring), and **mechanisms** (research questions or hypotheses about why certain strategies or tactics work or do not work). Metrics can tell us what was done to engage participants, markers can tell us what outcomes were achieved, and mechanisms help us link the two by helping explain how engagement activities yielded the desired outcomes. We suggest that RMCs consider using Getting to Outcomes^{4,5} or a similar approach to help design, implement, evaluate, and improve their engagement efforts.

Three Recommendations for Participant and Stakeholder Engagement

Based on the results of our interviews, site visits, and literature review, we make the following three recommendations that all RMCs should consider.

Implement the Following Six Recommended Best Practices for Engagement

Throughout the report, we present a much larger number of best practices for engagement and highlight engagement strategies and tactics that RMCs felt were effective. Below, we present an abbreviated “to-do list” of six engagement best practices that each RMC should consider implementing. It should be viewed as a foundation or a first step for engagement; RMCs, however, should carefully review and consider all other engagement strategies and tactics discussed in the report.

1. Expand existing community partnerships. To prepare communities for an upcoming national rollout of the AoURP, it is important to build awareness of precision medicine and prepare community members for considering enrollment in the AoURP. RMCs can use several tactics inspired by the literature on community-engaged research to pursue this goal—e.g., linking current, community-salient events to precision medicine; using community-level data to design an outreach strategy; and establishing project-specific advisory boards and eliciting input from them and other community stakeholders. These tactics not only help RMC engagement staff understand how the AoURP can suit community needs, but they also help build relationships of trust, respect, and mutual understanding that can facilitate next steps in the AoURP. As such, investing in community partnership could be viewed as a foundational engagement strategy that is crucial for ensuring engagement success at the community level.

RMCs that have expertise and experience with community partnering may be better prepared to work with communities in ways that will support the AoURP’s success. For example, they may find it useful to reach out to reputable community organizations that might be interested in

or are working on improving diets and fitness levels of their constituents and incorporate a discussion of precision medicine in these efforts. Nonetheless, even RMC engagement leads or staff who are entirely new to partnering with community groups may benefit from building stronger relationships within the community. Building partnerships is not simple or intuitive, so RMC staff with less experience in community partnering should actively seek mentoring and support from others with more experience. And, because partnerships always need to be renewed and revised, this mentoring should be ongoing. The AoURP may need to ensure availability of some financial resources to support building strong relationships within communities at all sites because investing in community partnerships is likely to pay large dividends in the future.

2. Foster a spectrum of leadership support. In any innovative endeavor, well-placed allies can make enormous contributions to the endeavor's success. In the AoURP, an effective engagement approach may begin with fostering a spectrum of leadership support, which can be implemented using the following three tactics, among others: (1) showing visible support from senior health care system leaders, such as by encouraging them to enroll in the AoURP themselves, writing a letter to RMC staff to encourage them to sign up for the AoURP, or presenting at RMC-wide leadership events to build support for the initiative; (2) securing buy-in from clinical department leaders to get access to different clinic facilities and public spaces where engagement activities may take place; or (3) working with the leadership to adjust operational policies to provide protected time for RMC employees to participate in the AoURP. Each of these efforts to build support from the top will cascade throughout a health provider organization and encourage clinician and staff participation in the AoURP, clinician and staff championing of the AoURP, and positive word of mouth that may help sustain enthusiasm for the AoURP.

Many factors may increase the leadership's readiness to support the AoURP, including the AoURP's perceived credibility and trustworthiness, the expertise of staff who conduct outreach, and the resources that the AoURP can bring to the RMC. The AoURP may dovetail with related efforts in the RMC, such as a parallel biobanking effort or an interest in innovating around precision medicine. It will fall to RMC staff to find these linkages and communicate with the leaders on how the AoURP can be leveraged to support these other extant goals. RMCs will also need to keep in mind that, once granted by leadership, trust can be easily broken. Relationships of advocacy like these will need to be renewed and revised as priorities change. Relationship-building will need to be continuous if key leaders are to remain committed to the success of the AoURP.

3. Engage a mix of study champions. The strategy of engaging a mix of study champions can include involving physicians, other clinical personnel, community members, and enrolled participants as champions. Champions play several critical roles in the AoURP. They make enrollment work by connecting AoURP staff with potential participants in settings and contexts where the latter are prepared to receive the message of the AoURP. For example, finding a clinical champion who works at an emergency room may help establish an engagement base at

that location. Champions also provide a trusted, credible “face” for the AoURP that helps the study feel familiar and comforting. And they help knit together a sense of continuity in a participant’s relationship with the AoURP. Each time participants see the champion at different locations throughout an RMC for reasons unrelated to the AoURP (such as during the next doctor’s visit or when they come for routine bloodwork), participants can be reminded of their participation in this study. Champions can be present with participants at times and in contexts that the study staff may not be able to reach, such as during the check-in for an inpatient hospital stay; the champion’s presence can also bolster the participant’s relationship with the AoURP in the process. That is why champions should be involved whenever possible. They should be fairly compensated for their time, such as with protected time, stipends, or substantive professional credit, so that they do not feel exploited or taken advantage of.

RMCs and sites may need to adjust a champion strategy to their local context and integrate champions into the engagement team. Many sites began with one expectation about champions but quickly realized that other tactics were more consonant with their sites or were less intrusive. For example, focusing on physician champions proved to be less effective for one RMC than encouraging nurses to become AoURP champions. RMCs should consider offering a short, accessible orientation program to champions and gather data whenever possible about how well a champion strategy is working (e.g., number of enrollees tied to a champion, time invested by champion, participant perceptions of the champion strategy). RMCs and sites may want to consider how champions could help with retention, define a role for champions in the context of the national launch, and identify ways to thank champions for their contributions to sustain champions’ enthusiasm for the AoURP.

4. Make precision medicine relevant to participant and community priorities. Tailoring the AoURP message can be accomplished by making precision medicine relevant to participant and community priorities by presenting it as a tangible, comprehensible aspect of the real world. Analogies for precision medicine, like prescription eyeglasses or insulin dosing, are some examples of how the AoURP can be described in a resonant way to participants. Staff can also talk about the promise of targeting a treatment to an individual, of avoiding overtreatment by defining which drugs are needed and for whom, and of moving beyond imprecise categories like race when designing treatments. Engagement staff might suggest that precision medicine could explain why some individuals are protected from common illnesses, making it possible to predict an individual’s prognosis with more exactitude. Using active listening to gauge what may make the AoURP attractive to participants and tailoring the message may be effective for engagement. Teams could work together to review the analogies and potential future scenarios to share with potential participants during enrollment.

RMCs had considerable successes in tailoring and personalizing their messages to participants and communities; however, at most RMCs, these efforts focused on raising awareness and enrollment and not on retention. Moving forward, it is recommended that tailoring and personalization of messages for participants should be considered as a retention

strategy that can be implemented by sending thank-you and birthday cards, emailing newsletters that share relevant information, and (ultimately) returning results that are comprehensible and consonant with participants' preferences for learning about themselves.

5. Build an engagement team with diverse expertise. The strategy of building an engagement team with diverse expertise includes such tactics as hiring staff with marketing, customer care, or public relations experience who also understand community priorities and know the clinical sites where recruitment takes place. Doing so is crucial for the AoURP because this initiative is so different from traditional clinical studies that have specific clinical goals and inclusion criteria. Many sites and RMCs hired staff with unique expertise. For instance, in an urban context, an RMC was able to hire engagement staff with foreign medical degrees who were awaiting medical training. These staff bring deep knowledge of precision medicine and (often) language skills. Engagement leads may want to consider using opportunities to hire staff who may be able to message the AoURP in a way that other team members cannot. Individuals with prior customer care skills may be likely to have outgoing personalities and the ability to withstand uncertainty and rejections while remaining upbeat about the project's goals.

No single staff member will bring all necessary skills to the table, and engagement leads will likely learn from their staff's experiences. Because the AoURP sites hire staff with different backgrounds, it can be challenging for all team members to immediately assume that other staff are appropriately prepared. Staff members may have biases in favor of their own backgrounds and need time to learn that others also bring strengths. Establishing and sustaining expectations that teams will be properly trained and will always engage in respectful collaboration and information-sharing is critical to engagement success. It may be effective to provide venues for staff members to present to their co-workers on their areas of expertise or personal backgrounds, such as in a seminar format or in a presentation format.

6. Be prepared to talk about uncertainties. The AoURP is designed to evolve over time; consequently, RMCs must be prepared to address uncertainty about the future. Indeed, the expected evolution of the AoURP might be framed as a strength: The AoURP is intended to be a learning context, as both participants and staff learn from their experiences and as the research advances. This expectation that RMCs and the study as a whole will learn over time entails particular responsibilities. That is, RMCs need to recognize the critical importance of keeping track of and discussing "open questions" at the local and national levels, focusing specifically on the areas of uncertainty that remain so that, as new decisions are made and as new facts are known, RMCs can immediately incorporate the new information in their work.

Consistently communicating about areas of uncertainty may help AoURP engagement leads and staff plan for the future. For instance, it is important to anticipate potential future roadblocks and opportunities. More than one RMC noted that their enrollment efforts have been successful to date partly because enrollment in the alpha and beta phases focused primarily on engaging with the most accessible groups of participants (colloquially discussed as "low-hanging fruit"), including friends, family, employees, and some patients. However, they are beginning to realize

that to engage a large and truly diverse group of participants, they may need contingency plans to enroll new individuals who had been initially reluctant to join or to access new populations for enrollment using an ethically appropriate strategy. Likewise, many RMCs are taking creative steps to localize enrollment efforts and will need to plan far ahead to obtain Institutional Review Board approval for these local adaptations. Simultaneously, sites may want to consider discussing anticipated future problems (not just current difficulties), such as retention approaches, plans for returning results and preparing clinicians to speak to their patients about these results, and the challenges of having participants return for future studies, particularly in communities with a wide digital divide. These discussions may affect how the AoURP and RMCs plan for follow-up communication with participants and address potential challenges with a digitally focused retention strategy.

Evaluate Engagement Success

Each RMC should consider ways to evaluate the process and outcomes of its engagement efforts. Evaluating engagement activities requires (1) defining a set of possible and desired outcomes, (2) measuring what was done to engage, and (3) identifying and testing hypotheses about how a given engagement strategy may lead to a desired outcome.

It may be beneficial to take an expansive view of desired outcomes of engagement, which may include increased levels of participants' **trust** in research, science, academic/research institutions, and medical facilities; improved **public perception of research**; positive changes in **health equity** in the conduct of biomedical research; increased levels of **scientific literacy**; increased **awareness of precision medicine**; strengthening of the **institutional relationships** within and between RMC sites; and **narrowing of the digital divide**.

The efforts to evaluate engagement success in the AoURP could yield important findings with high significance to multiple research fields. In selecting measures and outcomes to evaluate engagement success, the AoURP can test important hypotheses about how engagement in biomedical research can be improved because the mechanisms that link engagement efforts to their outcomes are poorly understood. Therefore, evaluating, for instance, whether it is the use of current examples of precision medicine (e.g., prescription eye glasses), cutting edge examples (e.g., tailored chemotherapy regimens), or hypothetical examples (e.g., designing a personalized diabetes drug) that generate the most enthusiasm for the AoURP can not only help RMCs identify which approach to explaining precision medicine works best for their pool of potential participants, but it can also help those involved in other precision medicine or longitudinal projects fine-tune their enrollment strategies.

Incorporate Retention Strategies

Throughout this project, we identified one gap in the AoURP engagement practices to date: how to retain enrolled participants over the course of this initiative by building a strong connection with them and retaining their interest in the initiative in the long run. To fill this gap,

we identified a series of best practices for retaining participants in longitudinal studies. We recommend that RMCs consider adapting these strategies and incorporating them into their engagement approaches.

1. Minimize the perceived burden of follow-up requests. Consider ways to reduce participant attrition when making requests for additional information from already-enrolled participants. Frequent requests for additional information may be perceived as burdensome by participants. The use of monetary and nonmonetary incentives may make participation in future studies that require additional data collection more appealing to already enrolled participants. Additional study design factors that may affect potential willingness to participate, attrition, and nonresponse include the length of time required for participation, the complexity of a task, and the amount of work involved in participating (e.g., a very long or complex survey); the perceived salience of a topic (whether people believe that subsequent waves of data collection are relevant to them, to their loved ones, or to a community); and participants' experiences in the existing study (e.g., a negative enrollment experience may lead to dropout).

2. Proactively manage the samples for future projects. Determine how to sample participants for future studies and agree on how potential nonresponse and requests for more data will be handled. For example, how much follow-up will occur when respondents fail to respond to a request? Is it possible to determine reasons for nonresponse (refusal to participate, incorrect contact information, other reasons), and how will reasons be tracked? At what point should requests for more data stop when participants do not respond? How do researchers handle situational nonresponse, when a participant cannot participate at a given time but can potentially participate in the future? These types of questions should be answered early on so that participants receive clear and consistent communication about their expected involvement and will be able to make a fully informed decision when they consent to participate in a follow-up project.

3. Manage the database with participants' contact information. Develop a strategy for keeping contact information for enrolled participants current. Although the minimum information needed is the participant's full name and email address, it may be helpful to request one or more telephone numbers, contact information for least one other person who knows how to find the participant, and details about that contact's relationship to the participant. Participants should be able to update their own contact information so that it remains current. A complete database should include logs of all contact attempts, as well as notes that include suggestions for future contact or notes about approaching the participant effectively.

4. Build relationships and stress the longitudinal nature of the project to encourage retention. It is important to inform participants from the outset and establish good relationships with them to normalize the idea that this study will require a longitudinal commitment. Participants are likely to stay engaged in the long run if there is follow-up and continued contact with the study organizers. This contact sustains feelings of trust and support for the study and self-motivation and altruism on the part of participants.

5. Maintain regular contact with participants to minimize attrition. Engage with enrolled participants regularly to show that they are valued and remind them of the benefits of staying engaged with the study. *Keep-in-touch exercises* (KITES) are one possible tactic for contacting participants between study requests to foster a sense of community and to keep contact information updated. Examples include updates about key findings, change-of-address requests, thank-you cards, and birthday or holiday cards.

6. Tailor and personalize messages. Identify ways to tailor outreach messages based on given participants' interests and invite them to propose ideas on what can be included in such messages in the future. It is important to make sure that when the AoURP is contacting enrolled participants, it does not always do so to ask for more information. Instead, the AoURP messages should emphasize study benefits, address participants' interests and preferences, and exercise cultural sensitivity while addressing community priorities.

Mapping the Future with the All of Us Research Program

The AoURP is an innovative research initiative intended to chart the future of biomedical science. It is creating what could be the largest and most diverse data set available for health research. Such data could make precision medicine a reality. Making potential participants aware of the program, enrolling them, and retaining them over a long period of time will require support from community leaders and clinical champions, as well as diverse engagement teams. Some potential participants are likely to be wary of such a bold national program. Therefore, critical first steps for participant and stakeholder engagement are to explain the program's goals and potential benefits in ways that participants can understand and to nurture an environment of trust with communities, as well as across and within RMCs.

Many important aspects of the AoURP are uncertain. For instance, what kind of information will the program be able to give back to participants, and when will it do so? What research questions will the AoURP data address? What role will the AoURP play in building precise and personalized health care in the future? Engagement staff must know how to talk about such uncertainties. But they can be sure that their investments in research, community wellness, and engagement are making a substantial contribution to improving our nation's health.

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Abbreviations

AoURP	All of Us Research Program
CAB	community advisory board
CQI	continuous quality improvement
EHR	electronic health record
FQHC	federally qualified health center
HPO	health care provider organization
IRB	Institutional Review Board
ISIA	Institution-Specific IRB Agreement
KITES	keep-in-touch exercises
NIH	National Institutes of Health
PAB	patient advisory board
PI	principal investigator
RAP	Rapid Assessment Procedure
RMC	regional medical center

1. Introduction

The All of Us Research Program

The All of Us Research Program (AoURP), a key component of the Precision Medicine Initiative launched by President Barack Obama in January 2015, is an ambitious and innovative research initiative led by the National Institutes of Health (NIH) to create a new large-scale research resource of health data that are being collected from one million or more individuals. Precision medicine is an approach to medicine that focuses on prevention and treatment strategies that take individual variability in genes, environment, and lifestyle into account.² The AoURP's mission is to revolutionize and accelerate health research and medical breakthroughs to make individualized health care possible by empowering patients, researchers, and health care providers to work together. The AoURP collects survey data, electronic health records (EHRs), physical measurements, and biospecimens (blood and urine samples), and, in the future, it will collect real-time data via wearable sensor technologies. By building one of the largest and most diverse data sets for health research, the AoURP is designed to change how scientific studies are conducted in the future. The idea is that researchers and citizen scientists will have access to de-identified data from a large and diverse group of volunteers to conduct studies that can shed light on social determinants of health and lead to future medical breakthroughs engineered to suit the individual patients who need them. By enrolling a million or more participants from diverse social, racial/ethnic, geographic, and economic backgrounds, as well as from all age groups and health statuses, the AoURP is trying to engage populations that have not been previously involved in research.

As a participant- and stakeholder-engaged data-driven enterprise that will support research at the intersection of lifestyle, environment, and genetics, the AoURP is positioning itself as a new way of conducting scientific projects in which

1. Participants (e.g., human subjects) are research partners involved in study design.
2. Participants have control over whether and how their data are being used.
3. Participants have the right to the results from their data.^{6,7}

Interested participants can enroll in the AoURP either (1) as direct volunteers through the AoURP website or the smartphone app or (2) at a participating health care provider organization (HPO) that is affiliated with one of the regional medical centers (RMCs), federally qualified health centers (FQHCs), or Veterans Affairs Healthcare Centers. The All of Us Journey, a 45-foot mobile educational unit that provides information about precision medicine and the AoURP, has been traveling across states to engage potential participants who do not live near one of the participating HPOs. This report focuses only on participant engagement that takes place at participating RMCs.

Seven originally funded RMCs (University of Pittsburgh at Pittsburgh; University of Arizona, Tucson; Trans-American Consortium; New England Precision Medicine Consortium; Illinois Precision Medicine Consortium; New York City Precision Medicine Consortium; and California Precision Medicine Consortium) and three RMCs funded in summer 2017 (All of Us Wisconsin, Southern All of Us Network, and SouthEast Enrollment Center) link local hospitals and coordinate AoURP activities within their geographic area.

The AoURP adopted a phased approach to participant and stakeholder engagement. All sites at participating RMCs are required to go through alpha and beta phases to fine-tune their engagement approaches. Alpha enrollment phase takes place during the first two weeks of full participant enrollment, including the biospecimen collection, at each site. Different sites start the alpha phase at different times. While the first site started enrolling participants in June 2017, there are some sites that entered the alpha phase in February 2018. Alpha participants usually include “friendlies,” such as employees, family members, and friends. After the first two weeks of successful engagement, sites enter the beta phase, which continued until the national rollout, which began in 2018. The purpose of the beta phase is to initiate and test a range of participant and stakeholder engagement activities that RMCs would like to implement on a large scale after the national rollout. The expectation is that the national launch, with its focus on national awareness campaigns, will increase the number of participants interested in joining the AoURP at participating RMCs.

Participant and Stakeholder Engagement at RMCs

As of March 14, 2018, more than 30,000 participants (approximately 18,000 of whom have completed all enrollment steps described below) have been enrolled in the AoURP. Participating RMCs can only enroll individuals who have an EHR at one of their affiliated sites or provide consent for the future use of their EHR if they ever obtain one. A typical participant journey starts with learning about the AoURP. Those interested in joining receive an invitation code that allows them to enroll in the AoURP by completing an online consent process. After they consent, they provide basic demographic and contact information and complete a series of online surveys about their health, family, home, and work. Upon completing this step, participants are scheduled for an in-person appointment at a clinic where their weight, height, hips, waist, blood pressure, and heart rate are measured. They also provide samples of blood and urine. Only those who have successfully completed all the above steps are considered to be full participants. The expectation is that all full participants will stay involved with the AoURP for a decade or more. While all participants go through the same enrollment process, RMCs engage with potential participants in different ways, largely because of the difference in their patient populations, clinic environments, and location.

All RMCs pledged to prioritize participant and stakeholder engagement. Each Institution-Specific IRB Agreement’s (ISIA’s) Section 7, “Outreach and Engagement Material,” includes a

detailed narrative of planned engagement activities, such as plans for community events, outreach to health care providers, and use of digital outreach mechanisms (e.g., emails). In these agreements, RMCs describe the role for leveraging long-standing partnerships with communities and building and sustaining trust with diverse participants through ongoing interaction.

The AoURP's goals are not simply to enroll one million participants but also to engage all relevant stakeholders as research partners. According to the White House Precision Medicine Initiative Privacy and Trust Principles, the AoURP governance includes "substantive participant representation at all levels." Investigators should "create and maintain active collaborations among participants, researchers, [and other stakeholders]" throughout the course of the study. The AoURP aims to maintain "meaningful and ongoing engagement with the relevant stakeholders" throughout its course.⁸ Because of the uniqueness, complexity, and scale of this research initiative, it is particularly critical that the lessons of participant and stakeholder engagement in the AoURP be described and analyzed.

To address this gap, at the request of the AoURP leadership and with funding from NIH, RAND researchers conducted an ethnographic study of participant and stakeholder engagement in RMCs to develop a set of best practices for engagement. This report both identifies the range of engagement strategies and tactics used by RMCs (see Chapters 3–8) and presents a set of recommended best practices for engagement that all RMCs should consider implementing (see Chapter 10). Engagement in the AoURP comprises the tasks of making potential participants aware of the AoURP, enrolling them to participate, and retaining them within the program. In the context of an individual participant's journey through the AoURP, the phases of awareness, recruitment, enrollment, and retention occur sequentially, with one being a precondition of the next. Nonetheless, some engagement activities may be focused primarily on one phase, whereas other activities may be applicable across all phases. Because it may be difficult to determine whether an engagement activity primarily supports just one phase of the participant's journey, and because success in each separate phase will contribute to the AoURP's overall success, we do not categorize engagement activities as salient to any particular phase of the AoURP. Moreover, where illustrative, we indicate engagement activities that are primarily relevant to specific phases. We note that our interviewees revealed more information about best practices for raising awareness and recruiting participants than about retaining them largely because RMCs have just started the process of recruiting and enrolling participants.

Research Methods

To develop a set of best practices for engagement in a quickly changing project environment, we used a Rapid Assessment Procedure (RAP), which helps combine information from several data sources, verify emerging findings through triangulation, iterate between data collection and analysis activities, and inform relevant stakeholders of emerging findings in a timely manner. First, we conducted an integrative literature review to understand what a best practice is and

what strategies and tactics for participant recruitment and retention are used in biobanking and longitudinal research—the two types of studies most similar to the AoURP. This type of review is helpful for developing a preliminary conceptualization of the topic. Second, we supplemented the literature review with the review of the engagement plans RMCs submitted as part of their ISIAAs, the results of a Delphi consensus panel in which RMCs identified key factors that may affect engagement, and the findings from a self-assessment tool of study engagement practices completed by RMCs. In the second step, we relied on the analyses that were performed by the AoURP engagement team at NIH; we did not have access to raw data. Finally, we conducted telephone interviews with engagement leads from all but one RMC and made a series of ethnographic site visits to three RMCs that have shown early engagement success.

The first two steps helped us develop an analytic approach for determining what constitutes a best practice and learn about the plans that RMCs had for participant engagement. They also informed our approach to qualitative data coding and analysis. The last step was designed to explain what engagement means in the context of the AoURP, how its definition has evolved over time, what engagement strategies and tactics can be considered best practices, and how engagement and its success could be measured and evaluated (see the appendix for details of our approach to data collection and analysis).

Purpose and Organization of the Report

In this report, we share lessons from our examination of RMC participant and stakeholder engagement. Much of the report (Chapters 3 through 8) describes strategies and tactics for engagement that RMCs use and perceive to be effective. We describe these strategies and tactics to allow engagement teams to consider the range of options available to work on engagement. We also explain whether a given engagement strategy meets the criteria of a best practice. However, the ultimate goal of the project is to identify a set of recommended best practices for engagement (Chapter 10). All RMCs should consider implementing these best practices at their respective sites before the national launch. We note that the purpose of this project is not to evaluate how well RMCs engage and enroll participants or to conduct case studies to identify what implementation challenges they experienced.

This report has ten chapters.

- In Chapter 2, we define *best practice*, differentiate between engagement strategies and tactics, and present a conceptual framework for evaluating the effectiveness of different engagement activities. The conceptual framework distinguishes between metrics of engagement (measures), markers of engagement success (outcomes), and mechanisms of engagement.
- Chapters 3 through 8 present a detailed description of strategies and tactics that RMCs considered to be effective. Each chapter covers a different facet of engagement: laying the foundation, leading by example, capitalizing on health care infrastructure, tailoring

and personalizing communication, building and nurturing teams, and dealing with uncertainty. For each facet of engagement, we list corresponding strategies and tactics. In describing each tactic, we provide specific examples of what different RMCs did to highlight a range of engagement activities RMCs may want to consider. In each of these chapters, we present engagement strategies and tactics, explain their purpose, discuss conditions under which they might be effective, and state whether a given strategy met our criteria for best practices. We also highlight potential unintended consequences of using the tactics described in each chapter because some of them warrant a careful review and discussion. Finally, we discuss how engagement strategies and tactics could be tracked. Together these strategies and tactics provide a detailed story of how RMCs pursued the goal of participant and stakeholder engagement, which might be particularly useful for sites that are either developing or modifying their engagement strategy.

- In Chapter 9, we describe the markers of engagement success (outcomes) that RMCs think participant and stakeholder engagement in the AoURP may be able to achieve. Here we focus specifically on the outcomes that go beyond enrolling one million participants and illustrate the expected impact of engagement on participants, communities, the general public, and RMCs.
- In Chapter 10, we summarize study results by presenting three key recommendations for participant and stakeholder engagement: implement six recommended best practices, evaluate engagement success, and incorporate retention strategies. The information presented in this chapter should be treated as a “to-do list” for engagement. It may be particularly useful for those who may not have time to read the detailed analysis of engagement strategies and tactics we present in Chapters 3 through 8.

2. Defining Best Practices and Outcomes of Engagement

According to the AoURP Operational Protocol, *engagement* refers to “the broad range of interactions between the program, people, and awardees and other organizations. Engagement includes information sharing, consultation, involvement and collaboration in decision-making, and empowered action in informal groups or through formal partnerships” (p. 61).³ It comprises the tasks of making others aware of the AoURP, enrolling them to participate, and retaining them within the program. Engagement is more than one-way messaging to target populations. It is about building relationships with stakeholders and participants by soliciting input, sharing knowledge and information, building formal and informal partnerships, and collaborating with others in decisionmaking processes. **Because engagement is made up of multiple aspects, in this report, we describe engagement as having many facets.** By recognizing the relational nature of engagement, RMCs can better tailor their awareness, enrollment, and retention strategies to be more interactive and effective. In this chapter, we describe how we used data and findings from the literature to identify best practices for participant and stakeholder engagement. In addition, we propose a novel conceptual model that recognizes three aspects of engagement—*markers, metrics, and mechanisms*—that can be used to evaluate engagement success.

Best Practices, Strategies, and Tactics

As a first step in our analysis, we conducted an integrative literature review to provide a deeper understanding of what should count as a best practice for participant and stakeholder engagement in the AoURP. **A best practice is an effective, standardized way of performing a task that can work in a range of settings.** Ideally, designation as a best practice should be supported by the outcomes of an assessment, such as measurement or benchmarking. Bergek and Norman⁹ (p. 22), for example, define a best practice as something that is “better at delivering a particular result than any other process”; “better” could refer to either process effectiveness (e.g., achievement of desired goals) or doing things “properly.”

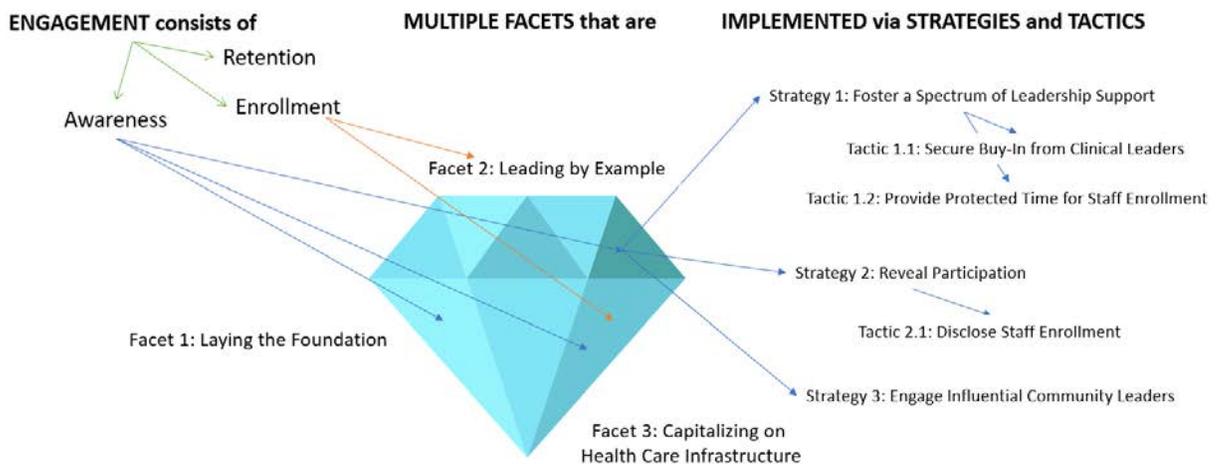
To develop a set of best practices for engagement, we distinguished between engagement strategies and tactics. The literature defines *strategies* as plans developed by practitioners for achieving their goals (the “what” of engagement—e.g., “our communication campaign will reach people via multiple touchpoints”). Strategies refer to “frameworks, techniques, and plans” that organizations use to survive, pursue their visions, and take advantage of opportunities¹⁰ (p. xv). In short, strategies are plans that an organization might use to achieve a goal. An organization can pursue a variety of strategies to work toward specific goals.

Tactics are defined in the literature as the way plans are implemented (the “how” of engagement—e.g., “we will send birthday cards with specific messages to the target population

as a way to keep them engaged with the program over a long period of time”). **Tactics are the concrete steps taken to accomplish strategies.** Tactics are context-specific and can be recalibrated or changed to better support organizational strategies. One strategy can have multiple associated tactics. The ability to execute a tactic effectively is more important than the volume of tactics that an organization employs. Measuring the relative success of a tactic involves accountability to both the timing (e.g., deadlines) and resource requirements within the context in which it is implemented. For example, if a tactic is proven to be effective, but an organization lacks the resources (money, manpower, time, etc.) to pursue it, it will probably not achieve the intended results.

For the purposes of this report, **we call *strategies* those activities that RMCs use to achieve a particular facet of engagement, and we call *tactics* the steps taken in support of a strategy that are tailored to fit a local RMC or site (see Figure 2.1).** In other words, because the AoURP includes many and diverse sites, we not only identify a set of strategies that represent shared means of achieving engagement, but we also identify a set of tactics that are context-specific. **Strategies are those approaches that should be useful everywhere; tactics are the adaptations chosen as optimal for certain kinds of sites.** For instance, all RMCs endorsed the use of a champion model in which specific individuals endorse the AoURP, offer information about it, and encourage others to enroll. A champion model is a strategy for engagement. However, sites chose different types of champions, such as community leaders, athletes, nurses, physicians, receptionists, or participants. Moreover, some sites tried one type of champion, but, after facing implementation challenges, they shifted to another type of champion. The use of different types of champions in different sites is a tactic.

Figure 2.1. Engagement Facets, Strategies, and Tactics



We identify best practices for engagement at the strategy level rather than at the tactic level because best practices should be applicable to different RMC contexts. While all engagement strategies described in this report *may* be useful at every RMC, best practices described in Chapter 10 *will* be useful at every RMC, and we recommend that *all* RMCs implement them. To identify best practices, we combined the results of our ethnographic site visits and interviews with previous literature on engagement. First, we identified and categorized the array of tactics and strategies adopted at RMC sites based on the facet of engagement they address. Then, we turned to the literature to see whether a given strategy was considered to be effective. Doing so provides additional information about what RMCs could do to effectively engage participants and stakeholders. We consider a strategy to be a best practice if it meets the following three criteria: (1) A strategy was used at more than one RMC site, (2) a strategy was deemed effective by engagement staff, and (3) a strategy was described as effective in relevant literature that we reviewed. In Chapters 3 through 8, we note which strategies do not meet all three criteria for a best practice; nonetheless, we consider these strategies important for RMCs to consider.

Next, we assume that RMC sites will tailor each strategy to their context through the customization and implementation of tactics. The literature is less helpful for explaining how strategies should be implemented; each RMC site is unique in terms of the populations it serves, the amount of resources it has, and the previous experiences with research participation that its staff may have had. Moreover, participant and stakeholder engagement is highly context-dependent. In lieu of guidance from the literature, we use interview and observational data to provide deeper insight into the various tactics that RMCs used to implement each strategy and why RMCs considered them to be effective. While these data provide a large number of possible ways to implement engagement strategies, as well as some contextual information needed to explain why a particular tactic was considered effective, in many cases, we still lacked rich contextual data that would allow us to determine the transferability of tactics to other sites. Where possible, we highlight the conditions under which a given tactic might be effective in addressing the goals that each strategy is designed to achieve. Attending to the level of both strategies and tactics can help RMCs consider whether and how to adopt or adapt a given best practice.

Three Ms of Engagement: Markers, Metrics, and Mechanisms

We propose a novel conceptual model for linking key aspects of engagement—**markers, metrics, and mechanisms**—which we call **the three Ms of engagement**. Each of the three Ms captures different aspects of engagement and its success, and all three together are necessary for tracking engagement process and outcomes.

Markers of engagement success: The AoURP is an innovative research program that is designed to change the way we conduct biomedical research and provide health care. The

AoURP's immediate primary goal is to collect data from at least a million people. However, the AoURP is likely to make many other important contributions, such as increased understanding of what precision medicine is; increased trust in science and medicine; and strengthening research partnerships between academic institutions, community organizations, and citizens, among others. **We define *markers of engagement success* as outcomes or benefits that engagement in the AoURP may bring.**

Metrics of engagement success: While markers are outcomes of engagement, metrics are measures of strategies and tactics designed to affect them. RMCs already collect a litany of quantitative and qualitative measures of their engagement activities, including the number of contacts made with potential participants, the time required for enrollment, the reasons for enrollment and study referral, and the types of successful champions used in different departments or sites. **We define *metrics of engagement success* as counts and descriptions of what was done to engage participants.**

Mechanisms of engagement success: While metrics can tell us what was done to engage participants, and markers can tell us what outcomes were achieved, mechanisms help us link the two. Mechanisms help explain how engagement activities yield the desired outcomes. **We define *mechanisms of engagement success* as research questions or hypotheses about why certain strategies or tactics work or do not work.** Currently, most of the markers and metrics of engagement in the AoURP are difficult to link. For instance, one can track the number of contacts with potential participants made by AoURP staff (metric) as well as the pace of enrollment at sites (marker), but the extent to which enrollment is shaped by contacts instead of by a variety of other factors (e.g., the features of the contact, the age or health history of the potential participant) is poorly understood. Similarly, while the volume and placement of AoURP-branded materials (e.g., ads, banners, promotional items [swag]) can be tracked, it is not clear whether these metrics affect enrollment in one direction or another. With regard to such markers as improving public understanding of precision medicine, the AoURP staff may have difficulty measuring any element of the process by which it is achieved.

We propose that the three Ms of engagement model can be used as a blueprint for an AoURP engagement evaluation. In Chapters 3 through 8, for each facet of engagement, we list metrics that RMC engagement staff either are tracking already or plan to track in the future. For situations in which engagement staff did not suggest metrics, we used inferences based on the literature and our findings to propose metrics. In Chapter 9, we describe markers of AoURP success (beyond enrollment) that RMCs think should be tracked. Finally, in Chapter 10, we offer some hypotheses about how engagement in biomedical research can be improved that RMCs may wish to test as the AoURP progresses.

3. Laying the Foundation

The AoURP is unique in its scope and reach and in the complexity of its underlying focus (e.g., precision medicine, genomic research, personalized health). For this reason, the RMCs all engaged in work that we have categorized as “laying the foundation” that prepares their communities for enrolling potential participants in the AoURP. This facet of engagement includes a variety of strategies that help increase awareness about and interest in the AoURP by creating a framework that makes the program accessible, understandable, and motivating to potential participants.

There is broad support for awareness-building strategies in health,¹¹ community-based,¹² and marketing¹³ research literature. The first step in enrolling for any health initiative or a research project is to define the target population.¹¹ It is helpful to start the enrollment phase by addressing the following questions: (1) Who are you trying to reach? (2) What behaviors or type of response do you want from your target populations? and (3) What will help trigger or influence the behaviors you hope to inspire?¹³ Answering these questions is a prerequisite for addressing the central question for enrollment: How will I contact the target populations?

The AoURP RMCs described who they were reaching out to prior to the national launch, which included a mix of patients with EHRs, RMC staff, their immediate family members, and friends. Some discussion also touched on how engagement plans may evolve once the national launch commences. Overall, the best practices for laying the foundation are not necessarily designed to directly boost enrollment and retain participants once enrolled. Rather, they are useful for building awareness and understanding of this complex research program and laying the groundwork for future enrollment activities.

Table 3.1 summarizes the strategies and possible tactics that RMCs thought helped them make potential participants aware of the AoURP. The table also lists the purpose of each tactic, as well as the conditions under which it may be effective. All three engagement strategies discussed in this chapter met our criteria for best practices.

Table 3.1. Laying the Foundation

Strategies and Tactics	Purpose	Conditions for Effectiveness
Extend Existing Community Partnerships		
Link current and community-salient events to precision medicine.	<ul style="list-style-type: none"> • Increase awareness of the AoURP. • Increase scientific literacy around precision medicine. • Increase interest in precision medicine. 	<ul style="list-style-type: none"> • Community partners provide an engagement infrastructure around health. • RMC and direct volunteer approaches to enrollment are connected.
Use data to select what community outreach activities to prioritize.	<ul style="list-style-type: none"> • Increase efficiency and effectiveness of outreach. 	<ul style="list-style-type: none"> • The RMC has access to high-quality data and partners. • The RMC has strong data analytic capacity.
Elicit input from community advisory boards (CABs), patient advisory boards (PABs), or other stakeholders.	<ul style="list-style-type: none"> • Obtain input on messaging and tactics. • Deliberate ethically complex issues. 	<ul style="list-style-type: none"> • Advisory boards already exist or can be formed quickly. • Advisory boards understand their scope of work on this initiative.
Expand Existing Institutional Partnerships		
Strengthen ties between sites within an RMC.	<ul style="list-style-type: none"> • Coordinate efforts within a local area. • Lay groundwork for future efforts. 	<ul style="list-style-type: none"> • Sites bring unique strengths to the RMC. • Some preexisting connections between sites exist.
Share resources within and between RMC sites.	<ul style="list-style-type: none"> • Leverage different resources at each site. • Optimize limited resources, expertise, and infrastructure. 	<ul style="list-style-type: none"> • RMC sites are willing to collaborate. • RMC sites are located relatively close to each other.
Embrace a Comprehensive Outreach Approach		
Provide tangible reminders of the AoURP.	<ul style="list-style-type: none"> • Remind participants and stakeholders about the AoURP as often as possible. • Build brand awareness and encourage retention. 	<ul style="list-style-type: none"> • The RMC has flexible funds to invest in swag. • Swag is perceived as useful by participants.
Embrace unique touchpoints.	<ul style="list-style-type: none"> • Integrate the AoURP into the context of clinical care. • Signal importance of the AoURP through multimodal communication channels. 	<ul style="list-style-type: none"> • Clinic staff and leaders are supportive. • Site-level signage policies are flexible. • Web design and other information technology capabilities
Tap into current and forthcoming national efforts.	<ul style="list-style-type: none"> • Increase efficiency of engagement efforts. • Ensure consistency of site, RMC, and national messaging campaigns. 	<ul style="list-style-type: none"> • RMCs and the national program office communicate and collaborate.
Ensure local relevance.	<ul style="list-style-type: none"> • Present the AoURP as resonant with communities. • Portray the AoURP as familiar and trusted. 	<ul style="list-style-type: none"> • The RMC has web design capabilities • RMC staff have graphic design skills and resources. • Local stakeholders are interested in supporting the AoURP.

Extend Existing Community Partnerships

Each of the RMCs was selected for the AoURP in part because of its network of community ties and successful partnerships with community organizations. Indeed, the literature suggests that partnerships with community organizations can be a useful component of a multimodal recruitment strategy.^{12,14,15} Yet it is a shift to go from collaborating with a community organization on a project about diabetes or prenatal health, which may feel immediately relevant to communities, to joining efforts for the AoURP's future emphasis on precision medicine and genomic research, where the direct benefit for individuals and communities may be years down the road. With the lead time enabled through the multiple phases of the rollout, the RMCs have initiated local awareness activities to talk about why the AoURP matters for community partners and set the stage for enrollment. RMCs described some of these activities during the interviews we conducted either during our site visits or by telephone. To preserve the confidentiality of our study participants, throughout this report, we use codes (RMC A, RMC B, etc.) instead of RMC names and do not specify whether a given interview was conducted in person or by telephone.

Link Current and Community-Salient Events to Precision Medicine

One tactic for extending existing community partnerships is for RMCs to **carefully attend to current community events and conversations to ladder in a discussion about genetics, genomics, precision medicine, and the AoURP**. For example, RMC I used the premier of *The Immortal Life of Henrietta Lacks* to engage its community in a conversation about medical research:

When we first started talking [about the AoURP] to some of the groups, the Henrietta Lacks movie had just come out. They were talking about how [and why] African Americans had been underrepresented in research, the Tuskegee debacle, and what happened to Henrietta Lacks. But once they got past that, they wanted to be the ones who made sure that their people were represented in [the AoURP] because they feel that it's going to be an important step for precision medicine in the future and they see the promise of that. . . . [T]hey want themselves and their family members to be part of it and be recognized.

RMC D similarly emphasized the importance of discussing precision medicine during community events:

[We] might do [a community event] like, maybe on diabetes, or on heart disease, or something that's not really tied to All of Us, but it's a way to show good faith and good effort within the community, and talk about how, you know, precision medicine could benefit diabetes, or heart disease, or whatever in the future. But another example is that when we met with the ministerial alliance, they wanted help with nutrition, how to cook healthy, and fitness programs for the members of their congregations. . . . That's something that we are planning to do going forward.

According to the literature, willingness to engage with the community around their concerns and in their contexts is a best practice within a community-based participatory project. Using the

existing community relationships and current events to initiate conversations about the value of precision medicine for the local community may help improve general scientific literacy and pave the way for greater understanding of the aims of the AoURP. Moreover, these actions may help to communicate the social value and future potential of the AoURP. According to RMC C, this tactic may become particularly useful when RMCs can serve as biospecimen collection facilities for direct volunteers or potential participants who do not get care at one of the participating RMCs and get credit for enrolling such a participant.

Use Data to Select What Community Outreach Activities to Prioritize

Raising awareness of the AoURP at large community events may not be efficient because a potentially large number of individuals at the event may not get care at participating RMCs and, consequently, will not have an EHR there. As an alternative to piggybacking on any community-based opportunity that may arise, RMCs may **identify specific locations that are likely to have high concentrations of RMC patients**—for example, by looking at the home zip codes of their patients. RMC I identifies neighborhoods where its patients live or work and sets up local enrollment sites there. This data-driven tactic helps it focus its awareness-building activities on specific high-yield areas and can consequently increase both efficiency and effectiveness of its outreach efforts because targeted community events are likely to expose eligible participants to the AoURP. The existing community partnerships can also help RMCs identify the locations where they should hold awareness-raising activities or learn how to determine where eligible patients may congregate. Alternatively, one site at RMC E gained the capacity to **create a new EHR** for participants enrolling without a prior visit to the RMC as a way of ensuring smooth enrollment of potential participants.

Elicit Input from Community and Patient Advisory Boards and Community Stakeholders

RMCs may also **consider forming and then engaging CABs** to guide their outreach efforts. CABs can provide advice on language, messaging, recruitment, and retention, as well as provide access to available community resources. By tapping into the collective wisdom of a CAB, RMCs can be more strategic with their outreach and communication efforts and tailor messaging appropriately.

To illustrate the usefulness of CABs, **RMCs used their CABs to avoid engagement efforts that might feel coercive**. The RMC H engagement lead mentioned the importance of CABs in helping to “understand diverse perspectives, some of which may be more negative” about biomedical research generally or the AoURP specifically.

RMC I found it useful **to rely on its hospital PAB to refine its communication strategy**. The PAB was a “large online patient panel of people who . . . had expressed an interest in giving feedback to [our site] specifically.” The PAB had previously completed a survey about who should deliver messages about research or other issues, and patient respondents indicated they would prefer that messaging to come from providers. The RMC used this information to focus on

engaging employees of the HPO during the alpha phase of the project and getting their support so that they would be aware of the program. It also used this survey information to design an advertising strategy that focused on providers. As the engagement lead said, “Some of them are wearing buttons [that say] ‘I’m One in a Million.’”

RMC H also **interviewed community stakeholders** to understand the difference between “people that just have questions, that are more reluctant [to enroll] but they could be engaged if you designed our recruitment in a different way” and “a group that just really doesn’t want to be involved at all.” While RMC H engagement activities were structured to suit the needs of the former group, this RMC developed for the latter group “respectful procedures for thanking them, for listening, for thanking them for allowing us to introduce the project and letting them know that they can reach us should they feel differently in the future.” These interviews allowed the RMC to “understand more deeply what the enthusiasm is about, what reluctance is about, and what refusal is about.”

In addition to interviews, this RMC also **used community events to allow potential participants “to discuss some of the controversies in more of a community setting”** and used CAB subgroups and elicitation techniques to allow CAB members to “prioritize what they think we should be doing in our recruitment or what they think the AoURP should be doing and its activities and how the AoURP’s results should be interpreted.” These activities with the CAB reinforced engagement staff’s understanding that **“We want inclusion, we don’t want coercion”** and helped them learn how to facilitate enrollment in communities with concerns about research.

Expand Existing Institutional Partnerships

In addition to leveraging community ties, the AoURP engagement staff may consider taking advantage of opportunities to expand partnerships and relationships within and across sites within RMCs, such as community hospitals, university-affiliated hospitals, university departments, and academic research centers. Expanding existing ties has been cited in the literature as being critical to successful recruitment of study participants.¹⁶ While the RMC B engagement lead described these institutional partnerships as “an arranged marriage” and maintained that it was still “learning how to work it out,” the growth and maturation of institutional partnerships was a key facilitator of AoURP activities overall.

Strengthen Ties Between Sites Within an RMC

The AoURP effort necessitates the establishment of mutually beneficial collaborations across multiple sites within an RMC that may have differing strengths and resources. RMCs include sites within academic institutions that focus on research, as well as clinical sites that focus on community-based patient care. For the latter, partnering with the former may be an effective way for their staff to participate in research and for their patients to benefit from these

efforts. For example, one RMC E site has not participated in research activities for nearly two decades. By joining the AoURP, its staff are now able to inform and lead recruitment activities. At RMC B, the AoURP offered a first opportunity for community providers to engage in research.

Relatedly, **academic institutions understood that the project could not move forward without the provider partners.** As RMC B engagement staff said, “The key element that’s creating the most benefit right now . . . is the development of these provider relationships internally. It’s so, so, so critical. It’s just allowing us access, if they allow for it, to just be able to work closely with the provider themselves, but also with their patients and their clinic staff.”

These partnerships may also transform institutional cultures within academic and community provider institutions in ways that soften biases and rivalries and promote organizational structures that facilitate collaboration. As the RMC B engagement lead explained: “It’s really important to measure that. . . . We launched this massive effort that tied us together and joined us at the hip in such a very, very public way,” and some of the institutional barriers—such as getting staff to have access to information at both academic and provider sites—took years to break through. Yet these closer ties are “a huge win . . . if you know how large organizations work, especially when you bring organizations together and both are risk-averse and trying to be careful.”

Share Resources Within and Between RMC Sites

Sharing resources among sites within the same RMC can also help extend institutional ties. Indeed, many RMCs reported doing so to facilitate the AoURP activities. For example, within RMC E, two sites shared a laboratory facility because the community hospital did not have adequate resources to handle the biospecimens. Two sites in this RMC also shared information about research opportunities that were rich in one site and sparse in the other.

These partnerships can prove valuable for helping achieve the engagement goals of the AoURP. As the engagement lead at RMC C noted:

[I]t’s important that [academic partners] hear from other institutions and hospitals about what they’re experiencing. And it will help us inform how we might modify our messaging for our institutions. So, in the spirit of sharing and understanding the effort behind all this, it’s really important that we all, you know, come together with a consortium-wide effort, so we can all be successful.

Similarly, RMC A drew on translational research collaborations, tapping into existing expertise and infrastructure in other research centers working on comparative effectiveness, clinical trial, biobanking, and epidemiologic research. **These collaborations allowed the RMC to build on a well-established framework for collaborative research to launch more seamlessly.**

Embrace a Comprehensive Outreach Approach

Several interviewees mentioned that the AoURP was envisioned as a digital-centric effort. However, many potential participants from underrepresented communities do not have email addresses or easy access to computers, and the multistage enrollment process involves online literacy. To address this challenge, teams have adopted a multifaceted, multiplatform outreach approach to accommodate the realities of the “digital divide.” The reviewed literature supports the importance of using comprehensive, multifaceted engagement approaches.^{11,17,18} Moreover, consistent with the marketing literature on building awareness, RMC engagement staff reported that **it takes “multiple touches” to plant the message about the AoURP**. RMCs need to develop interesting ways to seed the program across different environments to remind potential participants about the AoURP and prepare them to learn more about enrollment.

Provide Tangible Reminders of the AoURP

One component of a comprehensive, multiplatform strategy is to **creatively use swag and material objects, such as printed brochures, to inform and remind potential participants about the AoURP**. Doing so can increase both awareness of and retention in the program because swag and other material objects are props that trigger curiosity about the program. For example, RMC B found it effective to distribute AoURP-branded buttons, badge lanyards, pens, and water bottles to clinic staff as a way to express gratitude for their assistance in enabling clinic-based enrollment. However, these objects also inspired questions from patients who saw them and inquired about the program.

Moreover, several RMCs want to **use swag as a retention strategy, as a way to remind participants that they are part of an ongoing study**. They plan to give participants magnets, pens, or other small token objects that could stay in participants’ homes. As one site lead explained, “It’s not really about the gift. It’s a reminder and retention strategy” (RMC E). Teams saw these objects as a way to keep the AoURP at top of mind for participants after enrollment.

Embrace Unique Touchpoints

RMCs also found it useful to incorporate the AoURP messaging across patient touchpoints. One tactic could be to **integrate reminders about the AoURP into the context of providing care**. For example, RMC B found it effective to include information about the AoURP into hold-time messaging, encouraging patients to learn more about it during their clinic visit. Similarly, because many patients now engage with clinics through online portals, it could be effective to include information about the program and provide a link to the AoURP website on the hospital or clinic home page or the patient portal page where patients go to get test results or set an appointment. One of the RMC E sites, for example, posted the information about the AoURP on the intranet homepage for employees and on the patient portal that all patients used. It is working

on adding more multimedia about the AoURP on the intranet site, which will include videos with participants talking about the initiative.

Other creative tactics may include adding the AoURP messaging to meal trays (brochures and tray covers) in inpatient facilities, table toppers in the cafeteria, and video monitors throughout clinic areas (RMCs B, C, and E). **Messaging about the AoURP in different ways and at different patient touchpoints can help RMCs signal its importance.** Moreover, thoughtful distribution of messages about the AoURP can engage family and friends who might go to the cafeteria for a break or review a brochure left on a food tray while visiting a relative in a hospital.

RMCs may want **to post information about the AoURP outside of clinical settings.** These could include one-off events, such as taco trucks (RMC B), but also collaborations with long-standing community partners. RMCs may want to ask their community partners to post information about the AoURP in their facilities. For example, RMC E asked local community drop-in health information centers to include AoURP signage, host events about precision medicine, and place brochures for potential participants. Other RMCs were in discussion about outreach at major sporting events, trade shows, and other marquee events in town (RMC I).

Although this kind of outreach is typical of most community-based participatory research projects, **teams were often hesitant to promote the AoURP, given that many believed that a potential participant must have an EHR with the RMC site to become eligible for AoURP enrollment at that RMC.** They reported waiting for a national rollout before investing in such large-scale awareness campaigns.

Tap into Current and Forthcoming National Efforts

Integrating local engagement activities with the national campaign activities may be an efficient way to disseminate information about the AoURP. National resources, such as templates for different communication materials, stock pictures, and a list of frequently asked questions about the AoURP, were highly valued by the engagement staff we interviewed. Staff who had seen the All of Us Journey mobile unit, a traveling educational program designed to raise awareness of the AoURP, described it as an engaging way for people to think about precision medicine, and those staffing the mobile unit reported a lot of excitement from people who came through. The RMC C engagement lead was seeking permission to replicate in the staff office some of the interactive displays used in the mobile unit.

RMC staff also took advantage of the “one-stop shop for all things AoURP” developed by Wondros, praising the database of creative work that can be incorporated into site materials. Staff could pull Institutional Review Board–approved (IRB-approved) images and messages, sparing them the expense of design and ensuring a consistent “feel” to the program. The RMC A engagement lead said, “We’re using all of the Wondros-provided assets in all of this, so we’ll leverage all of that.”

RMCs may want to **consider proactively planning for the national AoURP launch**. Many interviewees mentioned their anticipation of the national media campaign that would dovetail with their own efforts to explain precision medicine, articulate the social value of the program, and inspire interest in participating. Moreover, some stated that a national effort would add legitimacy and credibility to the program. RMCs B, E, and I hoped to leverage the national campaign into local news coverage, morning shows, and other publicity opportunities to talk about the AoURP. Some were planning for increased enrollment volume and new kinds of inquiries, such as from those who might see a billboard or hear an ad on the radio. As the RMC B engagement lead said, “The staff that we’re bringing on now, we’re increasing our staff here to prepare for that [national launch]. We don’t want to be in reactive mode. We want to have everybody trained and ready to go.”

However, because RMCs are aware of the upcoming national awareness campaigns, some were delaying their own work until it could explicitly complement and extend the national messaging. Moreover, some RMC staff had high expectations for the national launch. One engagement lead anticipated that “we’ll have people calling us” and “I’m hoping that the recruitment won’t be as difficult for staff.” If staff now “work really hard to engage those people every day [by] going out and finding these people every day, my hope is that with the national campaign we’ll have people calling us as well” (RMC B).

Ensure Local Relevance

While there can be value to the national campaign, **RMCs suggested co-branding and localizing the AoURP materials**. This could include signage, brochures, and websites. Localized materials can help RMCs highlight their role as a trusted, known community partner and to include messaging they feel could best resonate with their communities. For example, RMC B suggested that the presence of the mobile unit in some communities might seem menacing or not inviting and that the federal imprimatur of the AoURP might generate fear or anxiety rather than bolster trust. Many RMCs thought it critically important that the AoURP have a trusted local “face,” and they pursued this in several ways.

While the Wondros database was a valuable resource for RMCs, these **templated materials may need to be modified to fit the local context**. To illustrate, RMC B included local people—including relatives of the AoURP staff—in the photos. Others featured known local leaders or individuals with racial or ethnic backgrounds that matched the diversity of the local community. This localization tactic also included generating signage in more than one language. Most RMCs preferred co-branding with national materials, such as by placing a site logo on a printed piece or adding a community identifier to the project title (e.g., “All of Us XYZ” in lieu of “All of Us”). Through these moves, engagement teams familiarized the program by connecting it with trusted local brands at every turn.

Some RMCs suggested building websites to showcase people in their communities who were involved in precision medicine initiatives. For example, the RMC E website featured

interviews with investigators of color or people from the community who had taken on interesting or controversial aspects of precision medicine. These efforts aimed to demystify who was behind the research. Other websites included testimonials from participants, community leaders, and health leaders who described the value of the AoURP for their communities and how precision medicine might impact local health concerns.

Possible Unintended Consequences of Laying the Foundation

There are several potential unintended consequences of pursuing these awareness tactics, most raised by the RMCs themselves. We note that RMCs are cognizant of them and are working hard to ensure that these potential challenges do not materialize.

Community partnerships take time to build and sustain. Moreover, they may carry over expectations from one project to another, leading community partners to assume that the AoURP will run like many other community-based studies. However, the AoURP is not like other projects. It varies in significant ways from many community-based studies—and herein lies a significant risk. If RMCs are not clear in detailing how this program is different from other research efforts, it might jeopardize the trust between community organizations and the health provider organizations. As an RMC E representative reflected, it took her 15 years to build a network of 72 partnerships in a community that has no reason to trust the clinics. She is wary of jeopardizing those relationships with a project that does not meet their expectations for being community based, given that many facets of the AoURP are governed at the national level.

In addition, **the understanding that AoURP participants must have an existing EHR at the RMC gave pause to engagement teams considering the use of traditional community-based outreach methods**, such as setting up information sessions or tables at religious services, local stores, or high-profile events (e.g., sports events). In fact, individuals without an existing EHR can enroll in the AoURP if they consent to the future use of their EHR if they ever obtain one. Engagement teams feared excluding other community members who might be at these locations or events. RMCs addressed this challenge by considering patient presence within neighborhoods: When the majority of people within a community received care through a site, the teams felt more comfortable leading these general awareness-building events. However, when the population of the area was more split between RMC patients and those of nonparticipating HPOs, they tended to shy away from these broader efforts. All expected this to change with the launch of the direct volunteer enrollment process that would allow those individuals who do not get care at participating RMCs to enroll in the AoURP.

Although creating an EHR for a potential participant who is currently not getting care at one of participating RMCs is a tactic used by some, it may lead to a situation where the amount of information in the EHR for that participant may be minimal if the EHR creation does not encourage that participant to get care at that RMC.

RMCs noted that **the wide reach of outreach channels and engagement tactics has the potential to confuse the message**. RMC I debated whether to set up tables at local sporting events, with some members arguing that sports are about health, while others stated that nobody goes to a professional sports event thinking about their medical records. The broad reach of precision medicine and the demands of enrolling one million participants might conflict as teams determine where and how to seed the message. Finding the line when an opportunity is “too much” will be something that each RMC must decide based on its community.

Representatives of RMCs B and C also mentioned the **importance of understanding resource allocation**. Prior to the national launch, the return on investment for doing something large-scale, such as public transportation banners, does not justify the effort. However, after the national launch, some laying-the-foundation strategies might evolve to encompass a greater range of local and regional media.

Finally, **localized branding has the potential to obfuscate the national nature of the study**. It is possible that people might enroll and misunderstand who will have access to their data. Moreover, localization might trap RMCs between the advice of their CABs or PABs and the requirements from the national office. For example, if the “Invisible No Longer” message is disturbing to or irrelevant within a specific community, what leverage will RMCs and sites have to alter the promotional materials? When will localized concerns outweigh national mandates? Establishing parameters that enable RMCs and sites to be responsive to their communities while maintaining some level of national brand integrity will be an important consideration moving forward.

Metrics for Laying the Foundation

Most measures of engagement that our interviewees were collecting tracked activities focused on laying the foundation. Interviewees described a wide range of approaches for tracking outreach and awareness.

Some examples addressed how people **tracked their reach at events and in other face-to-face interactions**. The RMC I engagement lead described tracking the number of contacts made at community and table events and tallying the number of interest cards distributed. In RMC E, recruiters track the number of enrollment codes that are given out to individuals and later used to register. Some RMCs reported collecting post-event feedback from participants. RMC D tracks the number of organizations that collaborated with it to organize community events. RMC A tallies how many people turn the RMC down (rates of refusal) and the number of attempts it makes to reach out to participants. RMC B also tracks the amount of swag given away at events.

Some interviewees described **digital metrics and tracking systems**, such as REDCap, which was a commonly used platform for tracking the number of participants who expressed interest and then enrolled in the AoURP. RMC C, which focused heavily on digital media in terms of outreach and enrollment, uses web analytics and tracks the number of interest forms

submitted online. RMC B used a “pre-interest” website, akin to an online interest card, which could then be tracked and yield leads to potential participants. RMC B attached unique bit.ly codes (unique addresses to a website) to handouts, cards, posters, and flyers so that it could track interest by event and location.

To improve their outreach and engagement activities, RMCs also **track participant feedback, including community input**. According to an RMC G engagement lead, the RMC keeps track of advice given during advisory meetings and how it responded to the advice. It also planned to survey CAB members to ask what they thought about participation. RMC A plans to do focus groups with participants and touch base with CABs.

With regard to data analysis, the RMC I engagement lead described **developing a visualization of engagement activities paired with enrollment data** to look for possible correlations between activities and bumps in enrollment.

Moving forward, RMCs may find it useful to follow the lead of RMC E and use A/B testing of different messages, tactics, and event locations to identify which ones are more effective in helping them reach their engagement goals. For example, RMCs may want to compare the effectiveness of different AoURP messages, such as “Invisible No Longer” and “Be One in a Million,” to see which generates more interest within a community. Alternatively, they can follow the lead of an RMC E site that tested whether adding a sticker highlighting the incentive to brochures increases uptake of the brochures and engagement with AoURP staff.

4. Leading by Example

The AoURP differs from other research initiatives in important ways. The AoURP asks participants to provide extensive personal data and to make a long-term commitment to an initiative whose aims are only broadly sketched; neither the information that individuals will learn about themselves nor the therapeutic discoveries that the AoURP data may generate can be precisely stated at this time. It is not surprising that some clinicians are reluctant to urge patients to participate in a study that may not offer them direct therapeutic benefit. One way to enhance the AoURP's credibility and trustworthiness is to highlight how it is supported by health leaders and prominent or trusted individuals from the community.

Literature on leadership^{19,20} and community-health partnerships^{21,22} supports the importance of this facet of engagement. *Governance, management, and leadership* are terms that define how an initiative or organization works. *Governance* refers to how organizations set strategic goals, manage partnerships, and provide accountability measures. *Management* refers to how strategies and visions are implemented, how conflicts are addressed, and how information is managed. *Leadership* is about influence over others. In particular, leadership is practiced through “management of meaning”—for example, determining the vision of an organization or initiative or shaping how people interpret goals. Within the leadership literature, the idea of leading by example captures how some senior leaders focus on embodying core organizational values; this is considered an effective way to motivate employees to also adopt those values.²⁰ Within the literature on community-based research, engagement of and support from influential community leaders are considered effective recruitment approaches.

Table 4.1 summarizes the possibly effective strategies and tactics for implementing them that focus on leading by example as a facet of engagement. The table also lists the purpose of each tactic, as well as the conditions under which it may be effective. We note that not all strategies described in this chapter met the criteria of best practices because they lacked support in the reviewed literature. For example, while our interviews suggest that encouraging program staff enrolled in the AoURP to reveal their participation is an effective engagement strategy, this is not a strategy mentioned in the literature we reviewed. Moreover, this strategy has a number of unintended consequences that we discuss at the end of this chapter. These potential unintended consequences should be considered before an RMC decides to encourage staff to reveal their participation. Although this engagement strategy did not meet our criteria for best practices, we still include it in our report because of the unique and innovative nature of the AoURP and the fact that some RMCs considered this strategy to be effective.

Table 4.1. Leading by Example

Strategies and Tactics	Purpose	Conditions for Effectiveness
Foster a Spectrum of Leadership Support		
Encourage visible leadership support from senior management.	<ul style="list-style-type: none"> Promote clinician and staff enrollment. Facilitate AoURP activities. 	<ul style="list-style-type: none"> Institutional priorities align with the AoURP goals.
Secure buy-in from clinical department leaders and staff.	<ul style="list-style-type: none"> Enroll from multiple clinical settings. Establish sustainable enrollment infrastructure. 	<ul style="list-style-type: none"> The organizational structure is decentralized. RMC liaisons have credibility.
Provide protected time for RMC employee participation.	<ul style="list-style-type: none"> Facilitate employee enrollment. Signal institutional support for the AoURP. Prepare and recruit study champions. 	<ul style="list-style-type: none"> There is institutional buy-in for the AoURP. There is employee interest in the AoURP.
Encourage Program Staff Enrolled in the AoURP to Reveal Their Participation*		
Disclose staff enrollment.	<ul style="list-style-type: none"> Signal the importance of the AoURP to all RMC visitors. Enhance the authenticity and persuasiveness of the recruitment messaging. 	<ul style="list-style-type: none"> Risk of coercion through disclosure at the site is low. Policies on altering clinical uniforms and badges are flexible. There is staff interest in the AoURP.
Engage Influential Community Leaders		
Consider both traditional and nontraditional community leaders.	<ul style="list-style-type: none"> Demonstrate the AoURP legitimacy and credibility. Capture the attention of people in different communities. 	<ul style="list-style-type: none"> Connections with a range of trusted community leaders already exist. There is community buy-in for the AoURP.

* This strategy does not meet all three criteria for a best practice, as defined in Chapter 2.

Foster a Spectrum of Leadership Support

Institutional leaders, such as top management teams within the RMCs or division heads, not only affect day-to-day operations but can also influence the degree to which the AoURP is viewed as a priority within the organization. A review of factors that influence quality improvement initiatives in health care settings showed that leadership support is correlated with initiative success.²³ The leadership literature suggests that when leaders of an organization enact organizational values and thereby lead by example, this can encourage employees to do the same.^{20,23,24} Encouraging leadership support for an initiative that is consistent with core organizational values is an effective way to motivate employees to participate in this initiative. Each RMC will be slightly different in terms of how senior leadership engages with the AoURP. For example, at RMC B, senior leaders provided wide-reaching, visible support across RMC sites because they wanted to build the consortium’s research profile. In RMC E, leadership was supportive of the AoURP because this study fit well with an ongoing organization-wide precision medicine initiative. In other instances where sites may be already deeply engaged in

other research activities, organizational leaders may have fewer incentives to prioritize the AoURP over other initiatives but may still support it by simply allowing the enrollment and engagement activities to proceed.

Encourage Visible Leadership Support from Senior Management

Depending on the context, RMCs used a number of tactics to build active leadership support for engagement. For example, RMC B found it effective to **give presentations about the AoURP for hospital C-suite executives, facilities managers, and other key gatekeepers**. Engagement leads from this site sometimes go as far as **encouraging senior hospital leadership to enroll** in the AoURP to help foster visible support and inspire others to sign up. In describing the effectiveness of visible leadership support as an engagement strategy, the RMC C representative stated that when “all the C-suite people [got] on board, they presented a letter of support and messaging to the organization. . . . ‘This [was] a big deal, and it’s very important, and we should all be on board.’” Similarly, another interviewee (from RMC B) commented on the influence that an email of support from the head of a clinical division in the RMC had on clinicians: “It’s been very heartening for us to see these elements of engagement that we have implemented with a lot of facilitation and guidance from [an RMC leader] who understands the [RMC’s] culture really well.” Indeed, **C-suite presentations can be seen as the first stage of engaging clinicians**.

Moreover, visible leadership support demonstrates how institutional leaders prioritize the AoURP in relation to other organizational endeavors. Leadership support can be particularly impactful for influencing the degree to which RMC employees enroll in the AoURP and voluntarily assist with the AoURP enrollment activities and motivating clinicians to tell their patients about the initiative. To illustrate, one RMC B site found it effective **to have top managers send an email to all staff underscoring their strong support for the AoURP and explaining how to enroll in the AoURP**; managers were also careful to indicate that participation in this initiative was voluntary and not connected in any way to an individual’s employment. This memo of support from highly respected leaders led to hundreds of employees contacting the AoURP staff within the next few days.

Secure Buy-In from Clinical Department Leaders and Staff

In addition to reaching out to senior leaders, RMC representatives we interviewed found it effective to **communicate about the AoURP with a wide range of clinic and department leaders and staff to secure their buy-in**. Several RMCs described giving presentations at clinic, department, and faculty meetings and to other affiliated groups, such as local research teams, as ways to implement this strategy. Other sites described holding events, such as ice cream socials, and encouraging AoURP staff to attend local research conferences where their RMC clinicians gave presentations.

Some sites also described the **importance of reaching out to nonclinical departments**: “There are presentations that we’re doing to culinary departments, environmental services, because many of them are employees of [the RMC], but they’re also [RMC] patients and therefore they would be within the catchment group of people that we’re thinking about” (RMC B). Similarly, at another RMC B site, the senior leaders sponsored a series of talks in which a range of speakers, including professors and physicians, presented on the AoURP and related topics to help educate nonclinical staff.

Securing buy-in from different departments or divisions within the RMC is critical for facilitating the work of the AoURP staff. In some settings, even the corporate C-suite leadership endorsements may not be enough to influence all institutional gatekeepers across an organization. Our interviewees recommended **understanding how an RMC is organized and what types of leaders and gatekeepers need to be engaged** so that participant enrollment activities could proceed smoothly. For example, in one location (RMC C), AoURP staff described having the “blessing” of senior leaders but faced resistance from facilities managers about placing signage in or near key locations. They were also dealing with a slow process of negotiating separately with each clinic within the RMC to get permission for the AoURP recruiters to speak with patients in waiting areas. This differed from other sites within the same consortium where the AoURP staff received blanket support to work with any clinic on site. Taking steps to **secure buy-in with a range of influential stakeholders** is important in terms of helping the AoURP staff work in both effective and efficient ways.

Provide Protected Time for RMC Employee Participation

In addition to communicating support, institutional leaders may want to consider **adjusting operational policies to support participation in the AoURP**, such as by providing protected or release time for employees to enroll. In many municipalities and medical centers, employees receive release time to donate blood. In a similar manner, institutional leaders could allow RMC employees to enroll during work hours, as suggested by one RMC C representative. Rather than asking employees to enroll during breaks or after work, this medical center was able to make enrollment activities convenient and allow its employees to enroll in the AoURP during normal business hours. This site representative said that for most RMCs, “their employees are their biggest asset [since they represent a big pool of potential participants] and that doing that employee outreach in the right way and making it convenient for employees to be able to do that is really sort of a key approach.” This engagement lead spoke with senior institutional leaders to emphasize that both managers and rank-and-file employees, including housekeeping and food service, should be allowed to sign up during work hours “because we’re a very diverse health system and we want to make sure that everybody has the time and the ability to do that.”

Accessibility is critical to participation in research;¹⁸ by taking steps to make enrollment more convenient for employees, managers can better support employee engagement.

Encourage Program Staff Enrolled in the AoURP to Reveal Their Participation

Encouraging program staff to reveal their AoURP enrollment was an innovative engagement strategy that some RMCs considered effective; nonetheless, it was not supported in the literature on biobanking and longitudinal studies we reviewed for this project. As such, it did not meet our criteria for best practices.

Disclose Staff Enrollment

Engagement strategies at some RMCs extended beyond fostering leadership support for the AoURP. RMC patients, the primary audience for the AoURP engagement activities, are unlikely to interact directly with RMC institutional leaders. Instead, their interaction will be limited to RMC engagement staff. Several engagement leads we interviewed noted that they **encouraged their staff to enroll as AoURP participants themselves**. Even some of those who did not encourage it thought that it may be beneficial for those **engagement staff who enrolled as participants to disclose their AoURP participation during recruitment activities**.

This type of **personal endorsement of the program is a very strong motivator** that may enhance the authenticity and persuasiveness of the recruitment messaging because, to a large extent, it erases the boundary between a recruiter and a potential participant. For example, engagement staff from RMCs B and C described how they plan to post photos or videos of themselves and their team members getting their blood drawn as a way to show what participation looks like. Moreover, going through the AoURP enrollment process themselves as participants allows engagement staff to better answer questions that potential participants have about the program and its requirements.

Because research participation is and must remain voluntary, it is inappropriate to require staff to participate in the AoURP. In our conversations with RMC engagement leads, no one described requiring staff to enroll as a condition of employment. Moreover, they train engagement staff on how to disclose their participation in the AoURP in a noncoercive manner when they interact with potential participants.

Engage Influential Community Leaders

Health and medical center leaders can be critical to building trust and interest in the AoURP, but community leaders can play a critical role by inspiring interest in the AoURP. Within the literature on community health, endorsements or information-sharing on the part of trusted community members lends greater credibility to a project.¹⁶ We noticed some unique examples of how community leaders were aiding the AoURP. Endorsements of the study from prominent community leaders who personally signed up for the AoURP were considered to be an effective strategy for broadcasting information about the AoURP to communities and getting communities

more engaged with research. As one RMC I representative noted, **including leaders from a community is an effective strategy for “establish[ing] trust that this study is a worthwhile effort**, and if those leaders are willing to say . . . I am one in a million too,” this will help “increase awareness and establish trust and lead by example.”

Consider Both Traditional and Nontraditional Community Leaders

Because RMC sites are different, it may be important to **consider seeking endorsement from a wide range of community leaders**. The literature notes that there may be a multiplicity of leaders to choose from; the nature of the study for which endorsement is sought will inform the types of leaders who will be most helpful.²⁵ For example, **local religious leaders** are commonly referred to as potential community leaders within communities where religion plays a role.²⁶ Such leaders can be effective in spreading information and building trust with community members, especially in African American and Latino communities.

These leaders can help demonstrate the legitimacy and credibility of initiatives like the AoURP and get the attention of people in different communities. For example, in RMC E, where one of the main community partners is a large church with a predominantly African American congregation, the minister’s wife joined this RMC’s CAB for the AoURP. The minister himself took to the pulpit one Sunday to extoll the value of the AoURP. During the sermon, he told the parishioners that this project would happen with them or without them, so they had to make sure that they were counted in.

Local celebrities, such as sports stars, could also help build awareness and establish the credibility of the AoURP in their local communities (RMCs B and I). Unlike more-targeted health initiatives, such as clinical trials, the AoURP can benefit from using mass marketing techniques, like celebrity endorsements or word of mouth, because the enrollment goals are high and there are no strict eligibility criteria for potential participants.

Possible Unintended Consequences of Leading by Example

Ethical and potential legal considerations underlie any interaction in which one person can influence the behavior of another. While visible leadership support and active encouragement to join the initiative can help increase enrollment numbers, outreach and communications from senior leaders to employees can seem coercive, even when messages underscore the fact that an employee’s job will not be affected by his or her participation or nonparticipation in the AoURP. **Leaders at all levels should be mindful about communicating the voluntary nature of the AoURP.** It is important to consider how employees may interpret their superiors’ endorsement of the initiative, to keep a record of any questions or complaints that employees may have about this engagement approach, and to recalibrate any engagement tactics that may turn out to be problematic. For example, employees may think they are being “voluntold” to do something, or that participation will help their careers in some way. Therefore, **it is important not to lose sight**

of the voluntary nature of participation in the AoURP, especially when RMCs are reaching out to employees as potential participants. This is why not all RMCs chose to use this strategy.

Encouraging AoURP staff to disclose their participation can also single out staff members who choose not to participate in this initiative, especially if the majority of other staff members have signed up. It can be harder for an engagement staff member who has not enrolled in the AoURP to signal sincerity in conversations with potential participants. In this scenario, a staff member should be prepared to respond to this potentially tricky scenario, especially if other engagement staff members are disclosing their participation during enrollment. Therefore, **attention should be paid to how potential participants and engagement staff members may react to personal disclosure of the AoURP enrollment** to address any concerns about this strategy in a timely manner. Overall, it is important for AoURP staff to focus on signaling authenticity and transparency in communication with potential participants to build trust.

Finally, nontraditional community endorsement may serve different purposes than traditional community endorsements; for example, a local celebrity may be helpful for building awareness at a regional sports event, reaching a wide range of people. The potential downside is that a portion of those people may not be ready to participate in the AoURP because, for example, they may lack an EHR or appropriate insurance coverage to be seen at the RMC. Thus, it is necessary to **consider the purpose, reach, and messaging of any endorser of the AoURP, as well as to consider how to manage complicated situations, such as interest from unqualified individuals.**²⁰

Metrics for Leading by Example

During our interviews, participants mentioned few specific examples of metrics they used to keep track of activities related to this facet of engagement. Moving forward, RMCs may want to **consider using such metrics as**

- the percentage of departments that have active AoURP supporters
- the number or percentage of clinics that support enrollment from their patient communities
- the frequency of reminders about the AoURP in intra-organizational communications
- feedback from staff participants about the relative convenience of participating in the AoURP and ideas for improvement related to organizational support for employees and potential benefits for future participants
- types of implemented organizational policy changes to facilitate staff enrollment in the AoURP
- assessments of policy effectiveness by comparing data about employee participation rates before and after a policy change
- the percentage of engagement staff who reveal their participation in the AoURP during recruitment

- feedback from participants, CABs, PABs, and other stakeholders about the types of community leaders they think would be impactful
- the number and types of community leaders endorsing this research program.

They could also

- follow up with senior leaders periodically during the study to gauge their views and solicit their ideas about leveraging institutional support
- follow up with other department heads and staff periodically to assess their views and ideas about the AoURP.

5. Capitalizing on Health Care Infrastructure

As a facet of engagement, capitalizing on health care infrastructure refers to using health care facilities, their surrounding medical and academic campuses, and the people within them to support engagement efforts. By virtue of engaging participants in health care settings, RMC staff are better able to explain the initiative as being related to health, gather biospecimens, explain the role of EHRs, and talk about such issues as precision medicine at times when these topics are salient to potential participants. Moreover, by recruiting from within RMC spaces, teams are more likely to identify participants who have the requisite EHRs. This “health care halo” enables teams to craft engagement strategies across the different clinic spaces, supporting their enrollment goals.

The way a space looks and feels can impact how participants view the steps needed to enroll. For example, having AoURP offices within clinical settings helps communicate the clinical and health-related focus of the AoURP. As an RMC B engagement staff member noted, “I think part of why people are not too concerned about [being asked to provide a blood sample] is a lot of people go to the doctor anyway and get blood samples drawn.” This individual suggested that participants were less likely to raise questions about the study requirements (e.g., blood draw, volunteering clinical information) because they are consistent with the activities that routinely occur in those settings.

At another level, the AoURP gains legitimacy and credibility through its association with trusted local institutions. The literature generally defines *credibility* as the degree to which people trust someone or something—for instance, a source of information. Estrada et al.¹⁷ describe credibility as how researchers demonstrate that they, and their work, are legitimate and trustworthy to audiences—for example, by having a credible institution associated with a study. *Legitimacy* is “a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions”²⁷ (p. 574). Health care institutions and health care providers tend to have relatively high credibility and legitimacy, which is why engaging a mix of study champions within RMC clinical settings is a best practice for engagement. By positioning the AoURP throughout clinics and affiliated spaces, the program becomes yet another facet of a trusted, credible local institution.

As we detail below, RMCs adopted strategies to capitalize on the multiple spaces within clinics and their affiliated areas (college campuses, outlier buildings, etc.). Within each space, they implemented a variety of tactics to engage potential participants described in the reviewed literature,^{17,27} including initiating conversations about the AoURP, using signage and visual materials located in highly visible areas, and partnering with AoURP champions. Nonetheless, we note that, in the reviewed literature, we did not see some of the engagement strategies that

RMCs consider to be effective, including recruitment from inpatient facilities and emergency departments. As such, some strategies that focus specifically on engaging with potential participants in different types of clinical spaces did not meet our criteria for best practices. While the AoURP is unique, these engagement strategies may be considered ethically problematic by some and may have negative unintended consequences that we describe at the end of this chapter.

Table 5.1 summarizes RMC-suggested strategies and tactics for how engagement activities can capitalize on health care infrastructure. It also lists the purpose of each tactic and the conditions under which it may be effective.

Table 5.1. Capitalizing on Health Care Infrastructure

Strategies and Tactics	Purpose	Conditions for Effectiveness
Establish a Base in Premium, High-Traffic Areas		
Use signage, tables, and swag to draw attention.	<ul style="list-style-type: none"> Remind participants and stakeholders about the AoURP. Build brand awareness and encourage retention. 	<ul style="list-style-type: none"> Site-level signage policies are flexible. There is buy-in from site facility managers. The site has flexible funds to purchase swag.
House operations in high-visibility areas.	<ul style="list-style-type: none"> Signal institutional support for the AoURP. Ensure convenience for participants. 	<ul style="list-style-type: none"> Appropriate space is available.
Recruit from Clinics		
Create a presence in clinic settings.	<ul style="list-style-type: none"> Integrate the AoURP into clinical infrastructure. Reach eligible participants. Frame the AoURP as the future of clinical care. 	<ul style="list-style-type: none"> There is buy-in from clinic managers, staff, and providers. Multiple engagement staff are available to go to one clinic site.
Take advantage of long wait times.	<ul style="list-style-type: none"> Increase engagement efficiency. Integrate the AoURP into clinical infrastructure. Reach potential participants who have time to hear the AoURP message. 	<ul style="list-style-type: none"> Clinic sites have predictable and consistently long wait times. There is buy-in from clinic managers, staff, and providers. Multiple engagement staff are available to work at one clinic site.
Engage potential participants before, during, and after a clinic visit.	<ul style="list-style-type: none"> Allow steps of awareness and enrollment to occur over time. Enhance privacy and participant control of enrollment process. 	<ul style="list-style-type: none"> Engagement staff are flexible with multiple outreach methods (e.g., telephone, email). Engagement staff can work outside normal business hours. Engagement staff have access to patient contact information. Potential participants are digitally savvy and can complete the consent process at home. There is buy-in from clinic managers, staff, and providers.

Strategies and Tactics	Purpose	Conditions for Effectiveness
Recruit from Inpatient Facilities and Emergency Departments*		
Work with gatekeepers to assess readiness.	<ul style="list-style-type: none"> Ensure that engagement efforts are sensitive and ethical. 	<ul style="list-style-type: none"> There is buy-in from clinic managers, staff, and providers. The degree of patient flow through inpatient and emergency settings is moderate.
Minimize physical burden on patients and loved ones.	<ul style="list-style-type: none"> Enroll both patients and family members. 	<ul style="list-style-type: none"> Mobile carts can be used to enroll participants and collect biospecimens.
Include the Wider Site in Engagement Efforts		
Include academic and support settings in outreach.	<ul style="list-style-type: none"> Enroll diverse participants. Increase enrollment efficiency. 	<ul style="list-style-type: none"> There is institutional buy-in for the AoURP.
Partner with other research programs and efforts.	<ul style="list-style-type: none"> Increase enrollment efficiency. Strengthen relationships with other research programs and efforts. 	<ul style="list-style-type: none"> Extant ongoing studies are willing to collaborate and share information.
Engage a Mix of Study Champions		
Engage physicians as champions.	<ul style="list-style-type: none"> Use trusted gatekeepers to access large numbers of potential participants. 	<ul style="list-style-type: none"> Incentives are available for champions.
Engage frontline staff in clinics.	<ul style="list-style-type: none"> Rely on champions with time and experience to engage potential participants. 	<ul style="list-style-type: none"> Clinic managers and providers support frontline staff as champions. Incentives are available for champions.
Engage other stakeholders in clinics as champions.	<ul style="list-style-type: none"> Increase positive word of mouth about the AoURP throughout a site. Use snowballing approaches to participant enrollment. 	<ul style="list-style-type: none"> There is institutional buy-in for the AoURP. There is community support for the AoURP.

* This strategy does not meet all three criteria for a best practice, as defined in Chapter 2.

Establish a Base in Premium, High-Traffic Areas

Having a **presence in a main lobby** positions the AoURP as a key part of a clinic and ensures that everyone who enters the building—patients, staff, family, and friends—sees the program name and has an opportunity to learn more about it. However, gaining attention in busy, high-traffic areas necessitates more than a poster or table. To make this strategy succeed, teams focused on **using signage to increase visibility and staffing teams appropriately**. Most of the tactics used in high-visibility areas are designed for awareness. As potential participants move toward enrolling, a separate area where participants can complete the consent process and biospecimen collection is needed.

Use Signage, Tables, and Swag to Draw Attention

Setting up a table in a lobby or foyer or near a cafeteria means high visibility, but not necessarily high attention. When people arrive at a clinic, they are typically focused on the day ahead. They are not necessarily looking to join a research program. Thus, the AoURP engagement teams may need to be visible amid the potential distractedness of staff, patients, and loved ones as they walk into and through these areas.

Working on the mantra that **it takes “five to seven exposures” to capture attention** (RMC E), several RMCs used signage to draw focus to their table or area within lobbies. For example, RMC B teams positioned 4' × 2' banners outside the main doors so that visitors' first encounter with the AoURP occurred before they had even entered the clinic. They followed this closely with signs on the entrance doors, followed again by larger banners within the main foyer of the clinic. Thus, by the time people get to the engagement team's table, they have had three potential encounters with program messaging.

One site at the RMC E set up a larger **display at the base of the main elevators that went to all clinics**. Their table, staffed by two or three engagement specialists, was covered with an AoURP-branded tablecloth and filled with brochures, an iPad playing program promotional videos, and several posters explaining the program. Notably, the staff at this table had no chairs and spent their time connecting directly with people as they walked past. We saw similar setups in the other two RMCs during site visits as well.

RMCs also put ample **signage in or near elevator banks throughout clinics**. One site worked with the security guards and information desk or guest services staff to provide brochures and maps to people who were arriving for scheduled enrollment appointments. But in so doing, they similarly ensured that these staff could be advocates for the program. Sites also placed **posters and table toppers in cafeterias and coffee shops within clinics and hospitals**. As people would take a break from other settings, they could read about the AoURP over a meal or coffee, as explained by the site lead at RMC B.

Finally, sites often included **some kind of “swag” as an enticement** to come to the table. This was often something as simple as an AoURP-branded bottle of water or pen (RMC B) or hand sanitizer or package of tissues (RMC C). RMC B tried things like ice cream carts, giving away frozen treats and brochures and talking to people about participating in the AoURP. Importantly, we did not identify any sites that advertised the \$25 participation incentive in these high-traffic areas. While it was listed on brochures and potentially mentioned in conversation, it was never the lead statement, nor was it highlighted boldly on signage.

House Operations in High-Visibility Areas

A few sites went so far as to **base their program operations fully within a high-visibility area**. For example, at RMC C, one site established its program work space within an open clinic area right next to the main elevator banks and the cafeteria. This made it easy for everyone to

find it. Moreover, people frequently stopped by to ask directions to other clinics because there was no glass or door separating the AoURP staff from anyone passing by. While answering questions not related to the AoURP, staff gave them brochures and invited them to return later to learn more about the AoURP.

Another site lead was eyeing a massive atrium in the center of a clinic building that was often where friends and family waited for loved ones in surgery (RMC E). The atrium provided several advantages from her perspective: sufficient numbers of potential participants, distinctive spaces that enabled private conversations, multiple areas for brochures and signage, and an area in the back corner that could be curtained off for biospecimen collection. The RMC lead was in the final stages of securing permission to set up operations in the atrium at the time of our site visit (early 2018).

Recruit from Clinics

The most common strategy across RMCs was to recruit participants from clinics. This strategy provided some structure to the messaging because staff could address the benefits of participating in the AoURP differently for those in a diabetes clinic versus those in a cardiology clinic. Additionally, a clinic partnership only happened when clinic leadership and physicians agreed to facilitate this arrangement. Finally, a clinic partnership required close working arrangements with the clinic manager and frontline staff. Thus, **when done well, a clinic partnership also created a network of supportive staff**, many of whom could and did enroll themselves. However, to succeed in these partnerships, the engagement teams had to be mindful of clinic structures, wait times, and other burdens on patients.

Create a Presence in Clinic Settings

Once teams solidify partnerships with specific clinics, the first step of participant engagement is **creating a visual presence in the waiting area**. One tactic for doing so is to hang posters on walls or, in smaller spaces, to stand smaller signage on end tables and coffee tables in the clinic. The purpose is to create a visual thread connecting the AoURP signage across a facility broadly—so that patients see it when they arrive, in the clinic, and everywhere they go.

However, **teams need to respect clinic managers in this decision**. As an RMC E engagement lead noted, “They just remodeled this entire clinic, and they won’t let us put anything on the walls. Nothing! So, we created these smaller [8.5” × 11”] images and put them in these stands here.” That team supplemented the posters with iPads that ran promotional videos for the AoURP in both English and Spanish. A site at RMC C had a similar experience where the building management did not allow them to put up any posters on the walls to preserve the overall aesthetics of the buildings. As a compromise and to show the leadership support for the AoURP, the hospital management allowed the AoURP program to put up freestanding posters and advertise on monitors throughout the building.

Engagement teams need to **coordinate with clinic staff to make the AoURP brochures available to patients**. Sometimes teams placed these on tables near other reading material, and in other clinics, they were situated near the checkout desk. “It depends on what we can do in the clinic,” as one RMC B stated. By seeding brochures throughout an area where people are often looking for something to read, engagement staff hoped to catch attention and interest among patients and their loved ones. Moreover, when laddered against buttons, badge holders, pens, and other tangible markers of the program used by clinic staff, the brochures offer an opportunity to ask about the program and participation.

RMCs also recommended sending **multiple team members to a clinic**. They reported that this signals credibility and “presence” in a way that is difficult to achieve when only one person undertakes the work: “To effectively recruit in inpatient units, we need to go as a group, and make our presence felt” (RMC B). Moreover, it can help teams reach enrollment goals when there is more than one person interested at a time (we discuss this issue later in Chapter 7). This is particularly the case when patients are accompanied by loved ones, providing opportunities to enroll more than one person at a time.

One RMC C site found it useful to **have its engagement staff wear white lab coats** during initial outreach activities, which signals that they are clinic employees and have a degree of authority or expertise. Two engagement staff in white lab coats spend much of their workday approaching people in waiting rooms, distributing brochures about the AoURP, and collecting contact information from interested participants. In this situation, wearing white lab coats allowed the engagement staff to blend with the rest of the clinical staff, which enhanced their legitimacy as employees in that setting. Nonetheless, engagement staff at RMC E opted not to wear lab coats because of the concerns that their role in the clinic may be misinterpreted. They thought that wearing lab coats could reflect poorly on the goal of creating authenticity.

Finally, **credibility in clinic settings can be signaled through branding**. Specifically, many teams wore items that included the AoURP logo, colors, and name. These may include giant buttons, badges, and badge lanyards (RMCs B and E). Such markers served both to distinguish team members from the patients and their loved ones and to solidify team members’ link to an institutionally approved program.

Take Advantage of Long Wait Times

Finding time for people to complete the AoURP enrollment process is one of the primary challenges facing engagement teams. The AoURP enrollment process is long—most teams reported that it takes anywhere from 30 minutes (for those who have completed the consent and survey processes online prior to their biospecimen collection appointment) to nearly two hours (for people not familiar with digital platforms or for those with multiple questions about the consent process). An obvious solution among many sites is to **partner with clinics that have long wait times**.

One RMC-suggested tactic is **to scope out clinics to assess their wait times prior to approaching clinic staff to secure access**. In this way, the time required to complete the enrollment process has a lesser impact on participants because they can complete the tasks while waiting for their appointment. For example, at one site in RMC E, clinic wait times often exceeded two hours, so “Having something to do while they wait, especially if it offers some financial incentive, is a nice thing.”

Nonetheless, the challenge with long wait times is that people may be hungry (fasting for bloodwork), tired, worried, or otherwise too distracted to be willing to properly engage with AoURP staff. All of these factors could be a barrier to providing informed consent to participate. As a workaround for some of these issues, a site in RMC C offers food vouchers. Another RMC E site, however, considered visit length and burden on patients to be major challenges to potential participants and declined to enroll patients from clinics that had long wait times.

Engage Potential Participants Before, During, and After a Clinic Visit

Other RMCs face a challenge of minimal or no waits within their clinical environments, especially as more sites adjust workflows to minimize patient waits. As an RMC D engagement lead mused,

When you reduce wait times, then you don't give people much of an opportunity. Because just as they get to the good part of the recruitment spiel, the person gets called back. And we know that if we do anything that slows down the workflow in the practices, we will get kicked out. We cannot do that. And so, you know, we're trying to think about how do we address that, and what else do we need to think about, you know? Can we give people something? Can we get them on the other end of the visit?

As suggested by RMC E, **one tactic may be splitting the awareness-building and enrollment activities**, starting the process in the waiting area, transitioning a participant to continue the efforts on their mobile phones back in the clinic rooms, and then catching them at discharge to finish efforts.

Another RMC-suggested tactic was to partner with clinics willing to share their patient schedules so that **engagement teams could reach out to patients by telephone in advance of their appointments to initiate the conversation** about the AoURP and to provide them with website information to do the consent process at home. Doing so may require engagement staff to make telephone calls at night or during the weekends. Once a participant agrees to participate, RMCs recommend checking the online portal to track the participant's consent progress and trying to schedule appointments for biospecimen collection either right before or after their upcoming doctor visit. Finally, they recommend meeting participants in the clinic to ensure that they arrive for their biospecimen appointment. The RMC E engagement team found pre-appointment telephone calls to be particularly effective for enrolling busy, computer-savvy, and well-educated patients in clinics with little or no wait time.

The added advantage of a **telephone call is that it provides a modicum of privacy to participants and minimizes any “contagion” impact of refusals.** At several RMCs (C and E, for example), engagement teams discussed the problem of having a very vocal “No” issued by a potential participant, which often had the effect of discouraging participation by others in the clinic waiting area: “One loud ‘No’ can effectively shut down a clinic for a few hours” (RMC E). By initiating the conversation with a phone call coming from a trusted clinic phone number, AoURP staff can squelch the contagion impact and initiate more-personal conversations than may be possible in some clinic settings.

Another tactic of recruiting from clinics with short wait times may be **working with clinicians to allow engagement to take place in exam rooms either right before or after a physician sees a patient.** For example, at one RMC B site, the engagement staff found it effective to be able to go into exam rooms while a patient was waiting for the physician to return (i.e., when the resident physician left the room to present the case to the attending physician). The enrollment staff would give the elevator speech to the patient in the exam room. If a patient was interested, a conversation would continue after the clinical appointment was over. This RMC engagement lead noted that this tactic works only when a physician is the AoURP champion (see the “Engage Physicians as Champions” section later in the chapter).

Recruit from Inpatient Facilities and Emergency Departments

Many RMCs are considering ways to **tap into the inpatient and emergency room settings** within their hospital networks. To an extent, hospitalized patients or those visiting emergency departments and their loved ones are a “captive audience” for potential engagement if teams can identify IRB-approved ways to respectfully and responsibly reach out to these individuals. In an effort to be fully inclusive, one site lead from RMC B explained,

We’re trying to get everybody the opportunity to participate, so it also gives them the opportunity, and, when you see the patients, you may eventually get some of the nurses consented as well and then their families, also.

RMCs that tried this method offered some specific tactics. Potential participants from inpatient units are less likely to encounter the engagement teams in other clinic spaces because their mobility is often limited, so engagement teams have been identifying ways to push messaging about the AoURP opportunity to these individuals and their support networks in ways that allow them to read and review materials in a thoughtful manner. For example, as an RMC B engagement lead explained:

[With] inpatients, you have a captive audience, essentially, and so what we are doing is providing a fact sheet and an interest card on a meal tray each day for our inpatients. And so what that allows is access to the information and they have a little time on their hands, many of them, and so they’re able to get questions answered and fill out the interest form. And so, the rounding that [my colleague]

described will also supplement that and provide a resource for people to have their questions answered.

The goal is to provide information in a way that is manageable considering the challenges of inpatient care.

Similarly, RMC E partnered with its sleep clinic to reach the overnight patients who stay on that unit each night. As the site lead described it,

We run our video on the television monitors and lay out brochures and relevant paperwork on the bed like at a hotel. They have 12 people per night, and they have nothing to do for hours.

Finally, recruiting from emergency departments might be an option to consider. Emergency departments have long wait times, and family members often accompany patients. Although not frequently used, considered controversial by some, and not supported by the literature, at least one RMC found that the AoURP message resonates well with emergency room and cancer patients:

When you tell somebody, All of Us research program . . . is the medicine of the future and the future, including now, that will give you the right medication for the right person at the right time But if you tell that person, instead of me using three [pills], I will know exactly because I have your information, your lifestyle, your environment, your analysis. I will know exactly. I will be more accurate to treat your disease, and I will only be giving you one. They love it. That's how I get people in the emergency room. They love it. They say, "Really?" They're fascinated, you can see in their—and that's how you sell this program (RMC B).

A representative of a site at RMC E noted that recruiting from the emergency department allowed the RMC to establish a relationship with a resident at a nearby transitional housing facility who shared the opportunity of enrolling in the AoURP with fellow residents.

Therefore, the main purpose of considering inpatient and emergency room settings as possible engagement venues is to give everyone an opportunity to hear about the AoURP, to take advantage of any opportunity to engage with people, and to seed interest in the AoURP. While these efforts may not always yield high enrollment numbers, team members argued that the work remains worthwhile if it presents an opportunity to make a positive impression on patients and their loved ones.

Work with Gatekeepers to Assess Readiness

Assessing the readiness of potential participants poses special challenges with inpatient engagement efforts. Many patients themselves may be quite ill, recovering from surgery, or distracted with multiple check-ins and assessments. While physicians may be the priority gatekeepers in some settings, some RMC sites recommended **working with unit nurses on inpatient units and emergency rooms** to determine which patients are sufficiently stable to complete the enrollment process and to handle biospecimen collection (RMC B). This RMC

suggested that “nurses often have a better handle on the condition of patients compared to doctors, so we learned to partner with them and trust their guidance. It’s working—our enrollment rates from inpatient are up.” By collaborating closely with gatekeepers, engagement teams continue to prioritize creating a positive experience for all potential participants in the hopes that, even if someone did not enroll from the unit, they would be more willing to enroll at another time.

Minimize Physical Burden on Patients and Loved Ones

When working with inpatient participants and their loved ones, it is important to **minimize any additional physical burden to the participants** to ensure that all enrollment activities could take place in their rooms. In this respect, several RMCs developed mobile protocols. Teams may consider using rolling carts to bring consent materials and even biospecimen collection to participants in inpatient units, rather than making them come to standard collection labs in other areas of the building.

Additionally, when working with inpatient participants, engagement teams cautioned that the enrollment process can be much longer and to plan accordingly. Teams reported that the process will be interrupted frequently by medical staff and that patients may need to “take a break.” This all results in enrollment processes that can take two hours or more. However, **accommodating the care needs of potential participants was the top priority for teams that engaged in this work.**

Include the Wider Site in Engagement Efforts

RMCs are vast, complex institutions, and tapping the full potential of those institutions can help teams reach their engagement goals. While students and staff are the primary focus of the alpha and beta phases, there is no reason to forget them once the national campaign launches. Specifically, students and staff may leave the RMC, and their replacements may not have had any contact with the AoURP effort.

Include Academic and Support Settings in Outreach

Connecting with staff and students across an RMC provides an ongoing pool of potential participants with connections to the institution. For example, RMC D did a major outreach to the information technology and administrative (e.g., human resources, billing) divisions at the medical complex. Geographically separate from the hospital, these sites are often a “forgotten” engine of clinical environments. However, these divisions also proved to be the most ethnically diverse within the medical center, and in reaching out through extended inclusive engagement efforts, the AoURP team won their support, with several individuals becoming key champions of the program within their wider communities. The same can be true of administrative staff, facilities staff, students, and their friends and families.

As for students, 25 percent of the university student population is new every year, and many receive care from RMC clinics. This turnover provides ample opportunities for additional engagement effort within a core community. An RMC E engagement lead noted, however, that the RMC gets the most resistance from students and faculty regarding the inclusion of EHRs in the study protocol: “My husband won’t join because of that!”

Partner with Other Research Programs and Efforts

Many RMCs were included in the program because of their existing research and/or biobanking programs. These parallel initiatives have proven to be effective venues in which to seed awareness about the AoURP and to capitalize on the shared resources and interests of an RMC. In several instances, interviewees recommended **piggybacking off communications for other studies as a way to reach out to potential participants who expressed an interest in participating in other research projects** (RMC H). According to one interviewee: “The most successful method [for us] has been when people call in for another study that they’re asked about this study as well. And we know that they’re already [our clinic] patients so we know that they’re eligible” (RMC F). Similarly, RMC C found it effective for a staff member working on recruiting for another project to introduce the AoURP at the end of the conversation. Those participants interested in the AoURP are then handed off to AoURP staff.

Engage a Mix of Study Champions

One of the effective engagement strategies is to **identify study champions or advocates among health care workers to support AoURP engagement activities**. Champions are those who “take an active interest and become involved in recruiting either directly or by allowing the researcher to use the champion’s credibility or authority in the community”²⁸ (p. 121). According to Shaw,²⁹ champions can be active in assisting with such activities as promoting, building support, or garnering resources for an initiative; facilitating connections between people or groups; and assisting with the organization itself—for example, when navigating potential organizational barriers, such as gatekeepers.

Champions differ from endorsers (see Chapter 4) in that endorsement implies a more passive role of communicating or broadcasting support for an initiative without requiring actual involvement in enrollment or engagement activities. An endorser could also be, but need not be, a champion.²⁸

The decision about who those champions should be may depend on the context of the sites. In the literature, **the use of champions is considered a general best practice for enrollment and retention**.³⁰ There are different types of champions, including administrative and community champions.³¹ Administrative champions are individuals from within an organization who can advocate for a project, assist with acquiring resources, or foster project development in some way. A community champion is someone from the target population who has credibility

and is respected by other community members. In addition to community champions, other people connected to participants, or even participants themselves, can act as champions—for example, by explaining the project to others or advocating for others' participation.³⁰ In the AoURP, RMCs most often find that provider champions are effective advocates.

Engage Physicians as Champions

Physicians can champion the AoURP in different ways. Indeed, RMCs B and C believe that **using physician champions is one of the most effective tactics of participant engagement to increase both awareness and enrollment**. For example, physician champions can write letters to their patients encouraging them to consider the AoURP (RMC E). They can also show their endorsement of the initiative by putting an AoURP sticker on their badge and then sharing information about it with patients during visits. Some physicians who may not be comfortable with directly promoting enrollment can still encourage their patients to speak with engagement staff and invite those staff to be present in their waiting rooms. For example, at some locations in RMCs B and C, engagement staff are allowed to shadow physicians to engage with patients during appointment downtimes. At RMC B, a physician champion allows RMC engagement staff to accompany him or her on rounds. As an engagement lead said,

Physician X might say, “Sure, you can come and round with me when I’m gonna go make my rounds on Floor 10.” . . . So we go with Physician X, we may have two clinical research coordinators rounding with that physician. She takes them into the room, introduces them, doesn’t do a whole big spiel on the study, more like, “This is this great program. . . . I just wanted to bring them in and introduce them. They’ll come back and talk to you if you’re interested,” and that’s it.

Clearly, not all physicians may want to become AoURP champions. That is why RMCs may want to create win-win situations and incentivize their physicians to participate in AoURP engagement activities. Doing so would require knowing what may motivate physicians the most. The type of incentives will vary, but here are some examples that RMCs found to be effective. **Physicians in some academic settings could be motivated to help if they get research credit (RMC B) or compensated time** (full-time-equivalent support) for working with the AoURP as champions (RMCs B, C, and E).

In RMCs C and E, there are initiatives under way to build out regional biobanks with the idea that collection procedures for the AoURP and their biobanks could be done in tandem in an IRB-approved way. So, if available, **RMCs may consider offering physician champions preferred access to biosamples collected in parallel with the AoURP’s samples or priority access to a regional biobank** to conduct their own research in the future in return for championing the AoURP.

Engage Frontline Staff in Clinics

In addition to having clinician champions, RMCs may want to **consider finding frontline staff members interested in becoming AoURP champions**. Patients spend a lot of time in waiting rooms, and frontline staff could become conduits of information about the program and encourage patients to consider joining the AoURP. For example, RMC G typically recruits frontline staff, like front office administrators and nurses, to help provide insight into how things are working and to assist with engagement workflow. RMC D held a meeting for a range of employees, including front desk staff and clinical staff, and unexpectedly found that the medical assistants became particularly interested in the AoURP. The RMC started calling this group “community ambassadors” and asked them to talk with their patients, friends at work, and neighbors. RMC E considered nurses and social workers critical to helping AoURP engage with patients.

Engage Other Stakeholders in Clinics as Champions

Stakeholders in nonclinical roles can function as effective study champions to share information about the AoURP through word of mouth and encourage those they know to enroll. This may lead to “snowball” sampling, in which the sample builds on itself through referrals. For example, RMC B recognized the importance of engaging medical center employees because not only are many eligible to enroll as patients at the site,

but they are also on the front line and can advocate for this program. Keeping them informed through emails from our top leadership, hosting our newsletter on the employee website, and anything from rounding to visiting department meetings and sharing information about the AoURP have been really helpful engagement opportunities.

Additionally, RMC E recruited security guards and staff at information desks to join the AoURP and encourage them to direct people to the AoURP clinic space.

Patients, participants, and community members could also be effective champions. RMC C staff encourages participants to use word of mouth to enroll other people from the local community. These participants spread information about the AoURP and actively encourage their friends and family members to come in and sign up. For example, some staff members at that RMC end a participant’s visit by asking them to tell their friends and family members who get care at that facility. One engagement lead described a mother engaged by RMC staff at a clinic with her adult son. The engagement team learned that her son used a wheelchair and required 24/7 assistance due to an adverse reaction to a medication he received as a child. The mother was consequently extremely enthusiastic about the idea of personalized medicine, as she thought it could have saved her child from his injury. Over time, she became a key advocate for the AoURP within her community, encouraging many referrals to the study. She was also invited to join that RMC’s CAB.

Unintended Consequences of Capitalizing on Health Care Infrastructure

Engaging potential participants in clinical settings may create an impression that their participation in the AoURP will have direct impact on the care they receive in a given medical center. For instance, RMC staff heard from a small number of participants that they assumed that they would receive results through their physicians or health records or would plan to speak to their doctors about genetic results, even though physicians may not have the appropriate training to interpret these results.

There are other **ethical considerations related to informed consent** that may also arise in situations in which participants give consent in health care facilities. Participants may not realize that they are consenting to participate in research rather than consenting to receive clinical care. Participants may fail to ask questions they would ask elsewhere, such as why a blood draw is required.

While there are clear advantages to working with known patient populations, staff, and associated friends and family, there are some important caveats to these engagement and enrollment efforts. **Inpatient and emergency room settings are clinical spaces in which patients and their loved ones may not be able to provide truly informed consent**, given the underlying conditions that have led them to these places. That is why following an IRB-approved protocol and engaging with nurses to understand the current health condition of a given patient are very important.

Additionally, even when enrolling fully functioning patients, **RMCs must consider patient burden**. Beyond time and physical burden, this could include other considerations, such as financial burden. For example, asking participants to travel back to a clinic setting for biospecimen collection can be taxing in areas with long commutes or significant parking fees. Some RMCs have considered compensating participants for travel costs and parking fees, but this can vary by the resources and policies of each site.

Finally, it is important to note that many sites felt that the complexity of precision medicine and the potential challenges of completing the AoURP consent process online almost always required an in-person conversation and assistance. RMCs need to determine whether self-administered online consent will be successful based on the level of computer literacy of their community and their familiarity with research involving personal health data obtained from surveys, biospecimens, EHRs, wearable sensors, and genomic sequencing. Indeed, some RMCs found it effective to schedule longer enrollment appointments in the AoURP office to allow for completion of the online consent process, online survey modules, biospecimen collection, and the physical measurement components of the enrollment process.

Although physician champions may play an important role in raising awareness about the AoURP, this tactic may not be always effective. For example, RMC B engagement staff said, “If you are waiting for just your physician referrals, we’ll never, ever get to a million. Physicians have too many other things on their plates.” There are a range of reasons why some

sites chose non-physician champions. In top-tier academic institutions, there are fewer external incentives or benefits for physicians to act as champions because the AoURP is an innovative infrastructure development initiative rather than a traditional research or clinical project. In community clinics, physicians may be too busy to take on yet another task. Moreover, physician advocacy of enrollment may be perceived as too heavy handed in the local context. RMC staff may want to keep in mind that a physician acting as a champion might cause patients to feel coerced into participation or a physician in a champion role might actually raise suspicions and discourage participation. That is why RMCs may want to consider engaging other types of champions, such as frontline staff, medical center employees, peers, and community members.

Despite enthusiasm for supporting the AoURP, it may be hard for frontline staff to find time to do extra tasks. This was an issue at one site in RMC C, where AoURP staff spoke to many frontline staff, like check-in clerks, who were originally willing to help and whose managers supported their engagement. This RMC, however, quickly found that even clerks who wanted to help ended up either not wanting to or not being able to do even simple tasks like handing out fliers or mentioning the AoURP.

It is important to **be aware of the connotations attached to signage and other signifiers of legitimacy.** For example, the use of white lab coats can be helpful but also potentially misleading because of common assumptions that people make about white lab coats and their association with authority. Such visual signifiers might enhance the recruiter's perceived authority but might also cause confusion about the recruiter's actual role and level of expertise within the health care environment. Similarly, while the fact that enrollment takes place in health care facilities may help alleviate concerns about EHRs, it may not help with other concerns that potential participants may have, such as an optional request for providing one's Social Security number (RMC C).

Metrics for Capitalizing on Health Care Infrastructure

Many RMCs reported efforts to evaluate the effectiveness of recruiting participants from different sites by **keeping track of the number of people that engagement staff were able to approach, the number interested in the AoURP, and the number who ultimately enrolled** in different clinical settings. They are continually on the lookout for new clinic enrollment sites that would fit their needs, and they all cultivated relationships with clinical staff to improve their success. In addition to measuring the effectiveness of recruiting from different clinics, RMCs reported measuring the effectiveness of enrolling patients from existing study registries, as well as the success rate of cold-calling potential participants. One RMC is using tailored website links (from bit.ly) assigned to different locations to assess engagement efforts from different clinic spaces.

Some RMCs tracked why people failed to enroll or dropped out. An RMC I engagement lead described tracking when people decline—for instance, when people declined because of

concern about medical records. The literature emphasizes how it is helpful to assess why individuals decide not to participate or why some choose not to proceed with follow-up requests over time. The literature on retention for health research initiatives includes many examples of tracking protocols for retention that include soliciting participant feedback. For example, some tactics related to participant feedback include the use of a database for logging contact attempts for every participant, including the date, time, staff information, tracking history notes, results of contact, suggestions for future contact, and notes about how to approach a person effectively.¹⁸

RMCs also reported **soliciting feedback from staff on tactics that may not be working for a particular clinic and on ways to improve engagement efforts in that location**. This information can help RMC engagement leads to ultimately make decisions about either leaving a particular site in favor of another or engaging with the clinic leadership to adjust their engagement activities. To illustrate, RMC C Site 2 reported adjusting its enrollment efforts based on how well it could fit within the setting unobtrusively. Instead of asking check-in clerks to hand out brochures about the AoURP to each clinic patient, it is now leaving brochures next to the check-in counter because check-in clerks were not distributing these brochures.

At this point, most RMCs tend to make enrollment-related decisions based on their staff members' best judgment rather than on systematically collected metrics. Moving forward, many RMCs plan to increase their data collection efforts to make more evidence-based decisions.

As for tracking champions, interviewees spent less time describing how they tracked, or planned to track, data on how engaged clinicians or medical center employees are. RMC C stated that it had not yet considered assessing provider-level engagement, but it could look at how many physicians referred patients, how many physicians distributed information about the AoURP to their patients, and how many of their patients signed up. In addition, tracking unique URLs on printed materials can help sites assess which types of materials or distribution locations reach more people. At RMC C, the enrollment process included a survey in which participants answered a question about how they first heard about the AoURP, which is one way to assess where people are learning about this program.

Collaboration with champions can also be tracked to help assess which types of champions are more effective and what types of activities have a greater impact on enrollment. For instance, it may be possible to track the number of referrals stemming from champions, the types of activities they assist with, how much time they spend on different activities, and ideas for improving champion efficacy.

Another possible approach to metrics includes **assessing and comparing conversion rates** (the number of enrolled people relative to the number of people contacted) **across different locations and at different times of day within RMC sites**. For example, at RMC C, a recruiter described how she had more success approaching people in waiting rooms in the morning than in the afternoon. By measuring the numbers behind these types of observations, RMCs can provide insight into when, where, and how recruiters can more effectively engage with people in their RMC site.

6. Tailoring and Personalizing Communication

The engagement staff strongly endorse tailoring and personalizing the message of the AoURP with potential participants and community members. Sites used a variety of tactics to do so. The literature on longitudinal panel studies attests to the importance of tailoring communication to enrollment efforts or shaping the communication approach to fit the target population.^{17,32} *Framing* assumes that “an issue can be viewed from a variety of perspectives and be construed as having implications for multiple values or considerations” and that people are able to “reorient their thinking about an issue” based on how the issue is presented to them³³ (p. 104).

According to the reviewed literature, tailoring communication is critical to recruitment and retention efforts. It is necessary to tailor communication to the target populations in general and to personalize communication whenever possible. The RMC engagement staff used both tailoring of communication to the target population as a whole and personalizing communication to the individual engaged in the enrollment effort. Personalizing communication includes using people’s names in email messages and finding messages in the moment that resonate with the individual hearing about the AoURP. Small personal details have been shown to help with enrollment and retention,³² such as knowing how to pronounce names properly over the phone or in person and keeping notes to recall specific details about participants over time.

Tailoring and personalizing communication are ways that RMC staff can bridge the gap between centrally generated, consistent AoURP materials and the particular interests of local community members. Understanding the cultural norms and values of a target population is part of the audience analysis process, which informs how one tailors outreach communication. Enrollment of hard-to-reach or vulnerable populations requires culturally appropriate outreach³⁴ based on “mutual respect, contextual knowledge and trust”¹⁶ (p. 55). These efforts align with the general movement in communications practice toward “narrowcasting,” in which focused, tailored messages are generated to have a message that “speaks to” a particular individual. Tailoring and personalizing communication increases the chance that a study is viewed as part of a local context, as opposed to seeming like an interloper. The engagement teams tackled tailoring in three ways: personalizing their connections to the AoURP, identifying value in the AoURP for potential participants, and crafting a compelling community narrative about the AoURP value.

Table 6.1 summarizes the engagement strategies and tactics used by RMCs to tailor and personalize communication. It also lists the purpose of each tactic and the conditions under which a tactic may be effective. While there is general support for tailoring and personalizing communication in the literature, not all strategies that RMCs felt were effective were mentioned in the reviewed literature. In general, there is more support for making the study relevant to community priorities than for actively generating participant interest in the study. To some

extent, this finding is expected because a research project typically has a known goal and focuses on a particular topic; the AoURP, however, is an infrastructure development initiative, and the topics of future projects that will use the AoURP data are not known at this time. Nonetheless, the literature supports personalization as an effective participant retention strategy.

Table 6.1. Tailoring and Personalizing Communication

Strategies and Tactics	Purpose	Conditions for Effectiveness
Share Personal Connections to the AoURP*		
Communicate that engagement staff are personally invested in the AoURP mission.	<ul style="list-style-type: none"> • Demonstrate confidence in the AoURP. • Communicate shared risks and benefits. • Promote long-term engagement. 	<ul style="list-style-type: none"> • Engagement staff are willing to disclose enrollment status. • Coercion to participate can be minimized. • Almost all staff have enrolled.
Link precision medicine to staff's personal interests.	<ul style="list-style-type: none"> • Explain precision medicine using real-life examples. • Frame the AoURP as the future of clinical care. 	<ul style="list-style-type: none"> • Engagement staff are willing to disclose enrollment status and other health details. • Coercion to participate can be minimized.
Make Precision Medicine Relevant to Participant Priorities		
Link precision medicine to the participant's personal interests.	<ul style="list-style-type: none"> • Increase motivation for enrollment in the AoURP. 	<ul style="list-style-type: none"> • Engagement staff are able to respect the privacy of potential participants. • Engagement staff are comfortable with hearing emotional stories from participants.
Explain precision medicine in the real world.	<ul style="list-style-type: none"> • Make precision medicine less abstract and more comprehensible. • Explain potential benefits of the AoURP in general and of enrollment specifically. • Increase scientific literacy around precision medicine. 	<ul style="list-style-type: none"> • Engagement staff have multiple analogies and examples available.
Make the AoURP Relevant to Community Priorities		
Emphasize the altruistic ends of the AoURP.	<ul style="list-style-type: none"> • Increase motivation for enrollment in the AoURP. • Explain potential benefits of the AoURP in general and of enrollment specifically. 	<ul style="list-style-type: none"> • This strategy can be used as a default engagement approach.
Emphasize the social justice aims of the AoURP.	<ul style="list-style-type: none"> • Increase motivation for enrollment in the AoURP. • Increase community buy-in for the AoURP. • Improve representation in biomedical research. 	<ul style="list-style-type: none"> • Local communities express social justice concerns. • Connections with a range of trusted community leaders already exist. • Engagement staff have credibility within communities.

Strategies and Tactics	Purpose	Conditions for Effectiveness
Emphasize the importance of studying environmental factors in the AoURP.	<ul style="list-style-type: none"> • Increase motivation for enrollment in the AoURP. • Increase community buy-in for the AoURP. • Address social determinants of health. 	<ul style="list-style-type: none"> • Local communities express environmental concerns. • Engagement staff are skilled in discussing environmental factors and health.
Use Personalized Messaging to Sustain Engagement		
Show immediate appreciation for completing the enrollment process.	<ul style="list-style-type: none"> • Improve retention and minimize attrition. • Improve participant enrollment experience. 	<ul style="list-style-type: none"> • Flexible funds to purchase swag and snacks are available.
Find ways to signal that each participant is valued.	<ul style="list-style-type: none"> • Improve retention and minimize attrition. 	<ul style="list-style-type: none"> • Participant retention is a priority. • RMCs and the national program office communicate and collaborate.
Personalize follow-on communication.	<ul style="list-style-type: none"> • Improve retention and minimize attrition. 	<ul style="list-style-type: none"> • Engagement staff can identify information of value to participants. • Infrastructure and capacity to track participants and send personalized communications already exist.

* This strategy does not meet all three criteria for a best practice, as defined in Chapter 2.

Share Personal Connections to the AoURP

One strategy for personalizing communication about the AoURP is for RMC engagement team members to open conversations with potential participants by sharing a story of why precision medicine, and this project in particular, matter to them deeply and personally. We note that we did not see this strategy mentioned in the reviewed literature.

Communicate That Engagement Staff Are Personally Invested in the AoURP Mission

One way of sharing personal connections may be for **engagement staff who enrolled in the AoURP themselves to explain why they did so**. For instance, RMC B engagement staff stated: “I’ve told them, ‘I’m part of it. My family and I have participated.’” She continues that the disclosure “immediately opens up that relationship because, ‘You know what? I’m here. I’m here as well as you. We are here together.’ That has been very powerful.” She went on to describe her own enrollment in the AoURP as “proof” of the value and promise of the AoURP: “[T]hat’s the connection that you make with them. Just telling them, ‘I’m with you. I’m here, and this is going to help our family, our kids, our generations to come, and I’m part of it, as well. I’m part of this family.’ So that, for me, has worked.”

Disclosing one’s own participation can engender trust and confidence in the program—particularly when staff and family are from the communities targeted for enrollment. As another RMC staff member said, explaining his own motivation to enroll tacitly communicated to the potential participant that he had deemed the risks to be outweighed by rewards and that risks would also be shared by AoURP staff rather than offloaded to participants only. Disclosure is a way for RMC staff to indicate that they will be figuratively alongside the participant throughout the AoURP journey.

Link Precision Medicine to Staff’s Personal Interests

Specifying the reasons for joining the AoURP may also be a useful tactic. Indeed, some RMC staff we interviewed not only shared the fact of their enrollment but also explained their reasons for it. The RMC B engagement staff member describing her own enrollment above said that, “For those that wish to hear, [I say that] we recently lost my 21-year-old niece to leukemia.” She and her family understood precision medicine as a way to improve the treatment or prevention of leukemia in the future.

Another tactic might be **hiring team members with biomedical interests and career goals.** This could range from offering internships for advanced undergraduates considering medical school (RMC A) to hiring physicians awaiting the transfer of international licensure to practice in the United States (RMC E). These individuals can use their medical knowledge to cogently describe recent advances in precision medicine, from chemotherapies to ophthalmology.

Finally, **asking engagement staff to share with potential participants how they imagined precision medicine might change their own health situation** may be effective as well. For example, one engagement staff member said, “My dad, my sister, and I have thyroid problems. My dad is 80. I’m in my 40s. My sister is in her 30s. We take the same medication. How can that be?” (RMC B). In these ways, staff drew on their clinical and scientific passion to describe the promise of the AoURP.

Make Precision Medicine Relevant to Participant Priorities

In addition to talking about their own link to the AoURP, RMC staff may want to **find the aspect of the study that would be of interest to potential participants.** During the interviews, many staff referred to the study as “precision medicine” as often as they called it “All of Us,” indicating the centrality of the precision medicine concept to their efforts. Therefore, spending time with potential participants to identify their personal connection to precision medicine may be effective for engagement. Indeed, a key task of the engagement staff may be to identify why a large-scale precision medicine study might be compelling and motivating to the individual in front of them. Literature on health initiatives describes the importance of culturally appropriate tailoring,³⁵ personalizing messages to address the local context or specific community needs,³⁶ communicating the salience of a study to potential participants,³⁷ developing a personalized

relationship between study staff and participants,³⁸ and personalizing communication to individuals broadly.¹⁷ For the AoURP, focusing on an individual's personal connections to precision medicine is a way of personalizing, or making salient, the AoURP pitch. Notably, such personalization techniques are also central to marketing and advertising literature in the context of using information about consumer behavior or preferences to better tailor products and services.³⁹

Link Precision Medicine to Participants' Personal Interests

The AoURP is a vast and ambitious effort to change the future of medicine. However, in the absence of an immediate and stable connection to a disease or community—such as diabetes, heart disease, or all people in a town or neighborhood—it is incumbent upon staff to **identify why precision medicine might matter for a particular person**. A core focus of their engagement efforts is active listening, which enables team members to hear what might be compelling, motivating, and worrying to potential participants. Identifying these stories can help the RMC engagement staff connect precision medicine and the project broadly to something personal and important to the potential participant.

Engagement staff can do this in different ways. RMC staff may engage in conversation about family histories of disease and risks in some populations. For example, an RMC E engagement staff member noticed a Holocaust tattoo on a woman and engaged her in a conversation about that, learning that she had no information about her family's medical history because of that horrific experience. For her, participating in the AoURP offers the potential for learning more about her genetic risks. Engagement staff may try to link the power of precision medicine to some element of the clinical setting in which they recruit—for example, discussing the next frontier of vision treatment with ophthalmology patients or tailored treatments for diabetes in the endocrinology clinics. Importantly, engagement staff must always be clear that no one can be certain about the precise clinical advances or benefits to individual participants that might result from their participation in the AoURP.

Of note, the AoURP mobile unit included a white board where visitors could post what they hoped precision medicine could do in the future. The mobile unit staff reported that participants' hopes included unlocking diabetes and heart disease and understanding the link between genes, environment, and autism. The white board did two things at once: It allowed visitors to articulate their own priorities, and it also shared those priorities with future visitors who built on them with their own. The use of information from such white boards may help RMC sites learn about the aspects of precision medicine that resonate the most with their participant population and use this information during engagement activities.

Explain Precision Medicine in the Real World

RMC staff may need to find creative ways to **make precision medicine sensible to participants and communities**. Staff can collect and share examples of current precision

medicine, as well as speculation on what it could mean further down the road. Several RMCs use the example of prescription eyeglasses as a real-world implementation of precision medicine. This was also one of the examples the mobile unit staff used. Other examples of precision medicine included advances in chemotherapy and in precision treatment for rare vision disorders.

Another tactic for explaining precision medicine is **pointing out the lack of personalized approaches in most therapeutics**. For instance, the RMC F engagement lead said, “Some of the examples we use [are that] we both go into the doctor right now and we both have high blood pressure, we’re probably going to get the same medication. But I may have side effects from that medication where you wouldn’t. And so in the future with precision medicine, we’ll know what medication is right for each individual.” Many RMC staff mentioned the importance of educating providers (who could potentially champion the AoURP) about precision medicine. Some RMCs were planning to **develop a continuing medical education module for physicians about precision medicine**.

Make the AoURP Relevant to Community Priorities

One of the more compelling ways to engage participants and stakeholders may be derived from **linking the AoURP to local community concerns or social aims** because a decision to join a study is made not only at the individual participant level, but also at the group and/or community levels, especially in underserved communities.³⁴ This is a standard practice in community-based participatory research where community priorities often guide the study focus and its activities.^{17,36,40} All RMCs put considerable thought into choosing signage or materials that fit community norms (e.g., “Invisible No More,” “I am one in a million,” non-English materials, photographs that reflect diversity).

Emphasize the Altruistic Ends of the AoURP

Connecting the AoURP to community members’ desires to help others could be a default engagement tactic. It is particularly useful in situations when engagement staff first approach a potential participant and do not know much about him or her. Engagement staff could **frame participation in the AoURP as a communal good**, serving an altruistic function by moving the whole community ahead. According to the RMC D engagement lead, the RMC D team had learned over the course of the project the importance of “really focus[ing] on the altruistic side of participating in a massive study like this that could help change the way medicine is, you know, change our health, and change the way that medicine takes care of people.”

Another tactic may be talking to potential participants about the AoURP as **a way to prepare providers to address the health of diverse communities** by including participants who are “highly diverse in race/ethnicity . . . [and] in terms of their backgrounds, experience, the region where they’re from, their histories and their perspectives on many things. . . . We’d like to see our clinicians and our health care systems be prepared for this [diversity] . . . and to be able to

provide the clinical resources . . . to answer the questions that people have in the future” (RMC H). As another engagement lead summarized the idea, **participating can be understood as a “gift to future generations . . . a legacy you get to leave”** (RMC B).

Emphasize the Social Justice Aims of the AoURP

A commonly used tactic is to **frame the AoURP as a project that furthers social justice by making biomedical research more inclusive and fair**. At some sites (though not all), the “Invisible No Longer” motto supported this social justice framing. This approach emphasizes how the AoURP is a way of including in research those who have historically been excluded. At one site that had a primarily African American population (RMC E), engagement staff frequently address mistrust and skepticism about biomedical research. Knowledge about historical abuses perpetrated on people of color strongly impacts engagement in such contexts.¹⁵ As another RMC engagement lead said, this context needs to be addressed proactively:

You need to know to put things in historical context. You need to know what things went wrong in the past because, if you don’t, you’re going to fail immediately. . . . You have to understand why people are worried about participating and you need to understand what happened before we had consents. . . . I think it’s naïve to think that just because you want to do the right thing and this is for a greater good that patients feel the same way. It’s how you message it which is really critically important (RMC B).

Another tactic to emphasize the social justice frame is to describe the AoURP as **an opportunity to right past wrongs**. For example, the RMC E staff tells potential participants in this underrepresented community that they need to get involved because “If we don’t get involved in an upfront manner, they will continue to do this behind our backs. We will be left out.”

Framing the AoURP through the lens of opportunity to be inclusive of “all of us” may also be useful. An RMC B engagement lead explained, “This is our opportunity to make sure that people who look like you—or us, and usually it’s an us—are involved.” This engagement lead asks potential participants, giving an analogy for medical therapeutics, “Do you really feel like wearing someone else’s shoes?” She continued by asking participants to choose between “being a trailblazer” as a participant or waiting as a nonparticipant to “talk about this ten years from now and ask why this [injustice] is happening.” As another engagement lead said, “I want people to be upset if they’re *not* invited to participate!” (RMC E).

Emphasize the Importance of Studying Environmental Factors in the AoURP

Other tactics to make the AoURP relevant to community concerns may include **tapping into engagement staff knowledge about the values of particular communities, such as environmental health**. Teams found success when they had a deep personal connection to the community and, perhaps, were living through these challenges as well. In contexts where environment concerns—such as urban pollution, dumping of agricultural chemicals, or mining or

oil industry waste—were relevant to communities, RMC staff found value in talking about environmental hazards and the possible lessons of the AoURP for identifying and understanding links between environmental exposures and health.

Use Personalized Messaging to Sustain Engagement

Engagement leads and staff stated that **tailoring and personalizing communications is particularly important for sustaining participants’ long-term relationships with the AoURP** upon their successful enrollment in the initiative. There is broad support for this strategy in the literature on longitudinal studies.^{17,37} RMCs pursued and planned a number of tactics for helping people maintain a strong tie to the AoURP. These tactics rely on connecting in personal ways with participants to remind them of their importance to the study. As one RMC B engagement staff said, “[Participants are] very aware of what research does and what it brings to the table. So they know that this is going to be something that they’re going to be interested in long term.” Personalized messaging sustains this interest and enthusiasm in the AoURP.

Show Immediate Appreciation for Completing the Enrollment Process

Many of the RMCs described a wish to **give something of value to participants immediately upon enrollment**. They described snacks, swag, or other token gifts as extremely useful for engaging one on one with participants in the enrollment process. Some engagement leads wished that health information could be immediately returned. As one said, “I really would build in like return of results or return of information. Some kind of return to the participant very, very quickly” (RMC G).

Emphasizing the value of the feedback form that gives the participant his or her basic health information (e.g., weight, body mass index, blood pressure) and **explaining the meaning of these results** at the time of enrollment may be important. While almost all engagement staff felt that these forms had value for participants, some felt that the information was so basic as to be of minimal value. Others felt that the information may be so new to some enrollees that “this would need education” to be sure it provided something useful to participants (RMC B).

Find Ways to Signal That Each Participant Is Valued

Finding opportunities to **recognize the value and individuality of each participant** may help sustain participation in the AoURP. For instance, one of the physician champions at RMC E felt strongly that “There should be a thank you for participating. Just a word of appreciation.” She anticipated that participants “need this feedback” and “expect to hear, ‘We’re proud of you and we appreciate you. Thank you for your gift and enrollment.’” She continued that, “tech[nology] engages you—even my apps send me birthday letters. Think about that, and parallel that.”

Some RMCs described plans in ISIAAs **to send post-enrollment thank-you notes, birthday cards, and “enroll-iversary” notes**. However, almost all RMCs were delaying implementing these personalized retention strategies while waiting for the national launch of the AoURP. As RMC B engagement staff explained, “We have plans, and once we get the national program going, we’re looking at a postcard.” This staff member described a program at a previous employer that sent a birthday card with a discount coupon included. Based on this model, “with that, you send them a birthday card, ‘Happy Birthday.’” RMCs considered these personalized retention strategies to be beneficial for engagement efforts, but most had not started to pursue them.

Personalize Follow-On Communications

Another way to sustain engagement is through **continuing personalized communications with relevant information, such as through emails and texts**. Signaling familiarity through personal address and name is one way to call attention to communications. Moreover, crafting relevant communications—for example, presenting work specific to a participant’s community or on a topic of interest—is another way to keep the AoURP “top of mind” with participants. More than one engagement staff member felt that nutrition information would be relevant to most participants. RMC B had created and distributed its own local newsletter that features recipes, events, and community news relevant to its participants. This newsletter is distributed by an email platform that allows it to track how many recipients open the email. Other RMC engagement leads considered using such systems as Salesforce or REDCap to efficiently create, distribute, and track personalized communications in the retention phase.

Unintended Consequences of Tailoring and Personalizing Communication

Certainly, tailoring messaging makes this vast and complex initiative personal and compelling. However, it runs the risk of distorting or skewing the message with every telling. **When the message a person is hearing about the AoURP is somewhat different each time, it can result in people holding differing ideas about the goals of and opportunities for participation.**

Moreover, **by sharing or seeking out personal connections to the potential of genomic research, participants might believe they will be helped by the project individually.** Specifically, there is a risk that participants could think that the project will identify and solve any looming health issues that will arise in their lives.

Each RMC implements and manages the activities related to the AoURP in a manner consistent with the high professional standards associated with conducting publicly funded biomedical research. In this regard, RMC staff recognize the importance of ensuring uniformity in process and structure across different RMCs so that participants across the country have consistent understanding of the AoURP regardless of the RMC that helped enroll them. While

RMC staff may use distinct messages to explain the AoURP to individuals during enrollment, the overall framing of the AoURP should be the same across all RMCs. Coherent messaging about health and the AoURP study aims are the primary means of ensuring consistency.

Consistent health messaging means making sure that communicators are sharing the same key metaphors, facts, and expectations with participants across all RMCs and modes of communication. It is very important to make sure that participants at any site understand that the AoURP is about the future of health and health research; that precision medicine holds promise for the development of innovative treatments; and that the AoURP aims to be inclusive, transparent, and stakeholder-driven. Participants should be told about the same set of activities required of them and should have similar expectations of information-sharing and feedback from the study. Consistency also contributes to perceptions of credibility because **consistent communication helps to build trust**. If messaging varies too drastically or is contradictory, this can be confusing or harmful to the credibility of the AoURP.

Metrics for Tailoring and Personalizing Communication

RMC engagement leads reported **tracking which tailored approaches seem to work** for them and for participants. Such evaluations are often informal, but all RMCs mentioned trying out different approaches to messaging and paying attention to those that seemed to be more successful than others.

More-formal metrics of tailoring and personalizing communication include using **A/B testing (RMCs B and E) to compare what types of conversations and messaging approaches work in a different clinic setting**. For example, RMC B used bit.ly to personalize links to its website that it attached to each communication effort (e.g., poster, table topper, specific event) to see which tailored messaging efforts were driving enrollment.

Some RMCs **tracked reasons for referral to the study** and aimed to incorporate those into communication with potential participants.

Across digital platforms, some RMC engagement teams tracked **open and click-through rates for different emails, likes and shares for different social media posts, and page-time and site depth for website engagement**.

Finally, several RMCs used customer relations management systems, such as Salesforce or REDCap, to efficiently create, distribute, and track personalized communications during the retention phase. By including such details as enrollment date, personal motivations for enrolling, enrollment site, and so forth, site engagement leads planned to offer both personalized messaging (birthday and “enroll-iversary” cards) and relevant cohort messaging (e.g., precision medicine advances in ophthalmology for patients recruited from the eye clinics).

7. Building and Nurturing Engagement Teams

For any health initiative, it is imperative to build an effective team to support project goals. In general, the team management literature suggests that a strong team should have a clear sense of mission or purpose and clear goals; a structure in which tasks are aligned with results; a collaborative climate in which people work together; competent team members with the right skills; appropriate standards of performance; support from the larger organization; and respected, principled team leaders.⁴¹ Ineffective teams often suffer from lack of unified commitment to a goal or mission, lack of collaboration, or lack of external support.⁴¹ For RMCs, it is necessary to assemble engagement teams whose members have appropriate skills and qualities, as well as relevant knowledge about how to get things done within their institution and contextual knowledge of the communities they try to engage. Additionally, it is important to support teams through effective team management, including listening to staff members' ideas and input.

Previous health research describes how building a strong team may require thinking about desired skill sets in different ways and ensuring that engagement staff develop these skills by offering appropriate training. Cultural competence^{32,42} (and, similarly, cultural sensitivity or responsiveness,⁴² culturally appropriate research,³¹ and understanding the cultural context of communities^{11,43}) is highly cited as critical for community health research. Rather than hiring only people with strong clinical or science backgrounds, Abshire et al.^{32,35} argue that a best practice for staffing longitudinal clinical research projects includes hiring staff with strong communication skills and knowledge of local communities. In addition to interpersonal skills for recruitment, other commonly cited qualities and skills include empathy,⁴⁴ which impacts how recruiters relate to participants; group communication competencies, including effective conflict resolution and consensus-building;⁴⁵ and the ability to work with interdisciplinary team members by focusing on (or training to improve) building shared meanings.⁴⁶

Through all of the interviews, we heard that the AoURP is not a typical clinical research project. Nor is it like anything else that people knew: biobanking, longitudinal studies, community-based participatory research, or disease-centric projects. With this in mind, the site leads spoke at length about the need to **rethink the kind of person who is the face and lead for AoURP engagement efforts**, as well as how all of those engagement leads work together toward the massive goal of enrolling one million participants. They identified four core strategies for building and sustaining engagement teams for this project: (1) Hire for diverse expertise, (2) hire resilient and outgoing staff, (3) experiment with different team structures, and (4) solicit and respond to staff experience. While there is broad support in the literature for strategies that focus on the expertise and experience of engagement team members, the literature we reviewed was less clear on how best to structure the engagement teams to facilitate participant enrollment.

Table 7.1 summarizes the RMC-suggested strategies and tactics for building and nurturing engagement teams. It also identifies the purpose of each tactic and the conditions under which it may be effective.

Assemble an Engagement Team with Diverse Expertise

To make the AoURP run successfully requires multiple skill sets: proficiency in engagement techniques, knowledge of consent and IRB procedures, collection of biospecimens, understanding of community outreach, knowledge of digital marketing techniques, ability to navigate institutional bureaucracies, and more. Although a given person may not have all of these skills, assembling an **engagement team whose members have different backgrounds** is likely to be a highly effective strategy. As an RMC B representative commented, “The mix of marketing, clinical, and community outreach perspectives are the ingredients for best practices [especially if] they build off each other and coordinate.” Therefore, hiring and training staff and assembling teams whose members can cover this range of needs are critical first steps to engagement success. Indeed, previous research recommends hiring staff with strong communication skills, cultural competence, and knowledge of the target communities.^{32,37} Staff training and quality assurance measures can also be tailored to assist with the context of research—for example, conducting mock recruitment interviews.³²

Hire Staff with a Deep Understanding of Community Priorities

Site leads across the RMCs stated that it is invaluable to **hire someone with deep connections to the communities of interest**. As the literature suggests, the relationship between research staff and participants can be critical for supporting enrollment and retention efforts. Smith, McNamara, and King³⁸ describe the importance of prepping participant mindsets from the outset and forming positive alliances with participants. Building relationships with participants also includes establishing rapport, having high-quality relationships, and maintaining staff consistency. At RMC B, for example, interviewees alluded to these issues by describing how they regularly tell members of the community that the AoURP is a long-term initiative and that they will be there for a long time.

At a basic level, understanding community priorities requires having **relevant language abilities**. As an RMC D representative noted, “I think we definitely want, we’re looking for people who are bilingual, but not just in Spanish. So, in Mandarin, in Arabic, in Haitian Creole.” Being able to approach and engage people in their preferred language is a key factor in facilitating trust and interest in continuing the conversation.

Table 7.1. Building and Nurturing Engagement Teams

Strategies and Tactics	Goals	Conditions for Effectiveness
Assemble an Engagement Team with Diverse Expertise		
Hire staff with a deep understanding of community priorities.	<ul style="list-style-type: none"> • Increase community interest in the AoURP. • Improve representation in biomedical research. • Obtain input on messaging and tactics. 	<ul style="list-style-type: none"> • Engagement team includes many members without ties to local communities.
Hire staff who understand the sites where enrollment takes place.	<ul style="list-style-type: none"> • Improve efficiency of enrollment. • Facilitate implementation of engagement and enrollment strategies. 	<ul style="list-style-type: none"> • Sites are highly bureaucratic, hierarchical, or complex.
Hire staff with marketing, customer care, and sales experience.	<ul style="list-style-type: none"> • Improve messaging, branding, and engagement tracking. 	<ul style="list-style-type: none"> • Site engagement staff have research backgrounds. • High-quality ethics and research training programs for staff already exist.
Hire resilient, flexible, outgoing staff and offer appropriate training.	<ul style="list-style-type: none"> • Minimize staff turnover. • Increase team problem-solving ability. • Increase staff job satisfaction. 	<ul style="list-style-type: none"> • Sites are highly bureaucratic, hierarchical, or complex. • Engagement staff use multiple outreach methods.
Experiment with Different Team Structures*		
Use the concierge model.	<ul style="list-style-type: none"> • Improve rates of completion of the enrollment process. • Support vulnerable participants throughout the enrollment process. 	<ul style="list-style-type: none"> • There is high participant concern about privacy. • There is high participant skepticism about research. • Participants have limited English skills.
Use the specialized model.	<ul style="list-style-type: none"> • Increase efficiency of enrollment. 	<ul style="list-style-type: none"> • Clinics are larger and have shorter wait times. • Participants have higher levels of trust in research. • Participants have more experience and comfort with research procedures.
Listen to Engagement Staff		
Touch base with field staff throughout the day.	<ul style="list-style-type: none"> • Use engagement staff efficiently. • Increase team’s problem-solving ability. • Improve morale and resilience among staff. • Increase staff satisfaction. • Improve staff safety. 	<ul style="list-style-type: none"> • Sites are large and complex. • Engagement teams are larger. • Sites are enrolling in clinics with long wait times.
Solicit and incorporate staff ideas regarding engagement efforts.	<ul style="list-style-type: none"> • Improve engagement effectiveness. • Improve staff morale and resilience. 	<ul style="list-style-type: none"> • Enrollment numbers are not high. • Sites are highly bureaucratic or hierarchical. • Sites have diverse engagement teams.

* This strategy does not meet all three criteria for a best practice, as defined in Chapter 2.

The value of fluency could go beyond translation and could help sites address the subtle nuances of understanding. For example, engagement staff at RMC E discussed the problems with using the phrases “pasaporte” and “Invisible No Longer” with the Latino community—raising concerns about immigration status and the goals of the program. By **prioritizing linguistic and cultural fluency in the hiring process**, RMCs can create an opportunity for all members of their communities to participate more fully.

Hiring staff with connections to community organizations may also be effective because such individuals bring credibility with potential participants, are politically savvy in their organizations, and are able to solve problems creatively and quickly. As an RMC G engagement lead noted:

What we want is people that have a long-time experience working in the community to being out in the field, quote, unquote, and who come from the background from the community. So they have to be local, having worked here and been very involved in doing community-based, community-engaged projects. It's very liberal criteria we use. It doesn't necessarily have to be in a health setting, but it has to be some kind of social service, or some kind of advocacy-type work that involves a lot of outreach and engagement . . . and being of the same cultural background. . . . we like some kind of congruence between the staff and the population that's being recruited. And . . . we ask them usually about what we call marketing or recruitment. What are creative ways that they've used to get people to participate in studies.

Hire Staff Who Understand the Sites Where Enrollment Takes Place

It is equally important to have engagement staff who **understand the nuances of each site and know how to navigate the different clinical environments**. Their ability to open doors—both metaphorical and literal—to clinic settings is invaluable as staff seek out the right enrollment environments. Having staff who understand the nuances of clinics, who know the routines and restrictions of clinical staff, who are familiar faces to patient populations, and who know the pacing of each clinic can help the engagement teams move more efficiently and effectively through the engagement efforts. This can be especially critical for RMCs with engagement leads who have been just hired to work at that location. For example, one site lead new to the facility raved about a team member who was hired from a clinical staff position within the site (RMC E). Her ability to know the different clinics, to understand how to move paperwork through the institution, to build on her existing rapport and relationship with patients, and to leverage her staff connections to secure new clinics was vital to the progress of their efforts.

Hire Staff with Marketing, Customer Care, and Sales Experience

The typical first path for most sites was to hire individuals with previous research experience, such as recruitment for biobanking or community-based participatory research projects, because that is standard practice for research projects. However, most site leads quickly learned that,

because the AoURP is not a typical project, staff with a different skill set could bring helpful expertise. Looking back at their engagement experiences, RMC engagement leads suggested **including staff with marketing and sales or public relations experience.**

First, hiring individuals with specific marketing expertise (RMC B)—communication design, strategy, and measurement—can provide the necessary heft to enable teams to develop comprehensive outreach programs while being strategic about their engagement efforts and return on investments. The sheer scale of this project and its multifaceted outreach efforts (digital, event, print, mass, etc.) necessitate a degree of sophistication about how to align the messaging, how to track its effectiveness, and how to understand points where it can be elevated or improved.

Second, hiring frontline engagement staff with customer care and public relations experience represents a significant shift from traditional clinical researchers but can better align with the demands of the AoURP work. The challenge of motivating individuals to join the AoURP is akin to the challenge of “selling” many products or services, especially if clients have never thought that they might need them. To use the words of an RMC E representative:

We need to hire people who love people. Whether you're an extrovert or an introvert, you should want to hear people's stories. I mean, this is a sales job. This is not a research [job]—you have to have really high attention to detail, but it is a sales job. And I think we forget that. And one of my physicians here—who has become a mentor to me since I'm so new to this—said, “You have to marry every single one of your participants.” And that seems silly, but you really get to know them. And I guarantee the people that we talk to will be committed to the program through the five years and beyond.

Hire Resilient, Flexible, Outgoing Staff and Offer Appropriate Training

Not every potential participant will want to join the study, and RMC engagement staff may need to approach several people before one of them decides to participate. They may need to reach out to the same person on more than one occasion to promote interest in the AoURP. Therefore, **hiring resilient staff who can withstand study uncertainty, changes, hurdles, and rejection and training staff on how to be more resilient** are important engagement tactics. While knowing whether a potential job candidate is resilient may be difficult, according to RMC representatives we interviewed, resilient staff members seem to be able to work well with others and see challenges as opportunities. For the AoURP, training on staff resiliency may be particularly important.

The changing nature of the project and the daily variability in the number of potential participants (e.g., some days in clinics where enrollment takes place are slower than others; people cancel their appointments, etc.) necessitate that the AoURP staff be flexible and have problem-solving skills. As we heard in interviews with the frontline engagement staff, the overwhelming response from potential participants is “No, thank you. I am not interested in this now.” Most reported hearing it upward of 20 times per day after they approach people with the

offer to join the program. Being continuously excited and upbeat about their jobs requires that engagement staff have a certain personality type. According to an RMC B engagement lead:

It takes a certain personality type to be shot down 20 times in a day and still be willing to go to one more person and talk to them and not be defeated. And that's not to say that there aren't days where somebody comes in and is like: "I don't know what happened. I don't know if I smell today, whatever I'm saying. Everybody's saying no to me!" And it's like, okay, that was your one bad day. Everybody's entitled to one bad, and now it's over. Tomorrow's a fresh new day. And they come ready to go in the morning. So really, I'm looking for people who are energetic, go-getters, easy to talk to. People who are passionate about the program [are] also really important because you can't sell what you don't believe in.

As such, it is critical that engagement staff be **resilient in the face of rejection and willing to attend to the next opportunity**. As noted above, the AoURP is not an easy initiative to pitch, and team members stated that it often takes multiple attempts with the same person before he or she is willing to participate in the program. Knowing this "five to seven touchpoints" mantra helps engagement staff move beyond each "No" and try again with another person.

Other RMCs used innovative approaches to inculcate this flexibility and resilience among their team members. RMC D recommended **training all engagement staff using improvisation techniques** because they help staff focus on what the other person is saying, promote flexibility in approaching each new person, and develop the skills for repeated engagements. Ensuring that staff possess these skills is crucial for engagement success:

We really need people that are very outgoing and are just comfortable sitting down talking to someone. . . . They've gone through the communications training that incorporates improv and more sort of theater stuff. But we also focused a lot on making sure that they had good skills around the biospecimen collection and that sort of thing. And I think we're realizing it's probably much better to spend much more time getting them comfortable talking with people and answering the questions that we now know people are asking than worrying about [finding the] top 1 percent of people that know how to do blood draws.

The goal of this training is to prepare staff to be comfortable with the diverse range of questions and comments that inevitably come their way during engagement work.

Traditional clinical research coordinators are exceptionally good at making sure that potential participants fully understand what they are consenting to when they sign up to participate in a study. They can also be skilled in lab work. Nonetheless, the RMC experiences to date suggest that traditional clinical research coordinators tend to be uncomfortable with the "pitch" process of direct engagement that is essential to the AoURP process. This led them to shift hiring priorities to **select outgoing individuals with strong interpersonal skills** rather than requiring potential job candidates to have previous research recruitment experience. Engagement leads often framed this as a "sales" mentality—a focused, extroverted, "can-do" approach to the work. As one site lead noted, "In the interview, they have to pitch me on All of Us. They have to make me want to join. It's a basic sales test" (RMC E).

Therefore, one tactic is **to train the staff with the right attitude toward the study on the science behind the AoURP** rather than to train traditional researcher coordinators on the “sales” approach needed to succeed in this engagement work. Explains a representative of RMC B:

We actually kind of changed our hiring focus a little bit over the past few months. So initially, when we were hiring a lot of our clinical research staff, we were kind of primarily targeted towards individuals that had clinical research experience, who had [previously] done projects similar to what we do here: biospecimen collections, physical measurements. But what we’ve been finding is . . . that the clinical research background isn’t quite as critical because we can train people. . . . Physical measures, we can train, work through those. Biospecimen collection, we can train on phlebotomy and collecting the urine and doing all of that. But I think the personality is kind of what we’re identifying as very, very critical in identifying someone who is able to go and capture the room, essentially. Or go in and really just be able to speak with somebody, understand, listen to them, and adequately communicate what the program is about and answer the questions the individual has.

Experiment with Different Team Structures

One way to accommodate the diversity of skills among engagement staff and to account for the multiple challenges of different communities and clinics is to adjust the structure of the engagement team and the enrollment process. We identified two consistent approaches to managing the enrollment process that require somewhat different engagement team structures: a **concierge model** and a **specialized model**. As noted earlier, however, we did not find specific recommendations on how best to structure recruitment teams in the reviewed literature.

The Concierge Model

In the concierge model, a potential participant works with one dedicated engagement team member for initial contact, consent, and final specimen collection. That team member becomes the point of contact and face of the AoURP for this participant. The concierge model may work particularly well for sites with very few engagement staff members. For example, one site had only three full-time engagement staff, so a one-on-one model was the only feasible option for such a small team. However, for other teams, it is a deliberate decision that allows for consistency and helps build trust with participants.

The concierge model can be especially valuable when participants are concerned about privacy (RMC E), when building trust with participants who are skeptical about research is important (RMCs E and G), or when language proves to be a barrier (all RMCs). The concierge model also ensures that team members fully understand the process, can perform all required tasks, and can find a rhythm and approach that works for them as well as participants. In addition, because there are fewer handoffs during the process, it can be easier to track data and any lapses in protocol.

The Specialized Model

In the specialized model, team members serve different roles according to their relative skills and strengths. For example, a member who is especially gifted in initial engagement might serve that role continuously. Once a participant has agreed to join the AoURP, he or she would be “passed along” to another staff member whose expertise lies in managing consent and all of the incumbent questions and details entailed in that phase. There might be one final handoff to an additional staff member who is good at biospecimen collection, including phlebotomy and handling, labeling, and storing specimens according to the protocol.

The specialized model holds potential for greater efficiency and enrollment success in that each team member is working to his or her core strength. This means that the outgoing person who is especially gifted in initial engagement can utilize that skill with more people because she or he is not managing the nuances of consent procedures with someone else, nor is the introverted consent expert forced to “pitch” the AoURP to many people every day. It also has the effect of bringing “heft” and “presence” to the project because it requires several team members to work together within a clinic. When multiple people with the AoURP branding on them (pins, badge holders, etc.) arrive in a clinic, “it seems more legitimate and real,” the RMC E representative noted.

This model is likely to work better in large clinics with shorter wait times and in sites with larger teams that can afford to hire dedicated phlebotomists who would not need to leave the lab to enroll more participants. We suspect that this approach would be far more challenging with only three staff members at a site. The specialized model, however, can help teams accomplish their tasks more quickly and also can manage the flow of participants from waiting areas to exam areas and back out. It can also help potential participants meet more than one AoURP staff member, which can be particularly valuable for retention if the participant’s only AoURP contact has left an RMC. This model is likely to work better when trust concerns are generally lower across potential participants—when a participant will not perceive a handoff as depersonalization or a lack of attention to care and participant experience.

Listen to Engagement Staff

Engagement team staff are on the front lines of AoURP engagement efforts. Their daily experiences are invaluable for understanding how to tweak the engagement strategy to better facilitate the overarching program goals. There are two engagement tactics that seem to work well: responding to in-the-moment staffing demands and creating opportunities for staff to share and reflect upon the work. Previous research has described how team meetings can facilitate knowledge-sharing—for example, the use of formal team meetings to gather staff observations to further the development of a health initiative.⁴⁷

Touch Base with Field Staff Throughout the Day

Teams should consider using a variety of communication tools to **communicate with field staff throughout the day**. RMC engagement leads we interviewed used messaging apps to communicate with each other while in clinics. Being in contact with field staff is particularly important for teams that recruit directly from clinics or lobbies and may be less important for telephone outreach. For example, during one site visit, we were touring with a team member when he received a text stating that the clinic selected for the day was “especially quiet—the residents are gone.” Because he knew that enrollment at another site was going full steam, he suggested that his colleague go to that site to support the team’s work (RMC E). Such periodic check-ins with the field staff during the day could also help team members who may need additional supplies and swag while out in a clinic area. By allowing team members to stay in place and continue their effort while awaiting support from “home base,” these communication tactics can help facilitate additional awareness-building and enrollment efforts without interrupting the flow of work.

Moreover, making periodic contacts with the field staff can have an added effect of providing safety to team members, should they find themselves in potentially dangerous or uncomfortable situations. While most sites send more than one person to a clinic setting at the same time, it is not unusual for team members to find themselves alone with a participant during the enrollment process. Should these situations ever turn uncomfortable, the communication tools allow team members to quickly and discretely call for support. One team member at RMC E acknowledged that she used the team’s app to “call for backup” one day when a conversation with a participant became particularly challenging.

Solicit and Incorporate Staff Ideas Regarding Engagement Efforts

Engagement work is challenging and can take a toll on even the most resilient, extroverted, and committed team members. RMCs identified a variety of ways to support their teams.

Engagement leads suggested **soliciting the input of the team members on how to adjust their work to be more successful**. Some teams conducted brief regroupings at the end of each work day. Others did longer regroupings at the end of the week. Most did a morning check-in to settle plans for the day as well. At RMC E, this included shifting the work schedule so that the teams could improve their success rates with telephone-based engagement. Others were keen to hold these meetings with site principal investigators (PIs) on a monthly basis: “It’s important that the PI hears from the engagement staff what they are experiencing on the ground” (RMC E).

After particularly challenging days and weeks, some site leads suggested hosting a more formal meeting to understand what is happening and to brainstorm ideas for how to approach the efforts differently. As one site lead noted,

I also think it’s really listening to [frontline staff] because I spend more time with the team than I probably should, but we’ve just been trying to get our numbers up. So it’s just been all hands on deck listening to them because their feedback is

terrific. While we went through a little phase of frustration where they kind of wanted it easy, and it's not easy, they're really motivated. All of them have a personal reason to be involved in this program. All of them are *underrepresented* (RMC E, emphasis original).

Sitting in on one of these meetings during a site visit (RMC B), we heard team members swap stories to try at initial engagement, recommend new clinics to consider, and help clarify responses to challenging questions.

Unintended Consequences of Building and Nurturing Teams

Identifying and hiring staff with all the desired skills may be time-consuming and can slow down the enrollment efforts. While there are certain skills or characteristics that may be hard to develop quickly, such as not being reluctant to approach a potential participant or having knowledge of local communities, appropriate training may help engagement staff to accept rejection from potential participants. Therefore, RMCs may benefit from offering resiliency training to newly hired staff rather than looking for job candidates who are already resilient.

Resilience and ability to easily engage in conversation with others is a great skill, so long as it can be tempered by a keen attention to the details of the IRB-approved protocol and a mindfulness about consent. If staff do not follow these requirements, participants may feel compelled to join or may feel like their “no thanks” is not being respected. Similarly, while engagement staff with customer care, sales, or marketing experience can contribute to the work of an engagement team, enrollment in the AoURP is not akin to selling a product. Engagement activities must always adhere to the highest ethical standards with regard to education, consent, and voluntariness.

Moreover, **whether a team follows a concierge or a specialized approach, there will be trade-offs for participants and compromises for the site.** In the concierge model, participants could become disillusioned or mistrustful if their staff member were to leave the project. The specialized model can lead to disjointed teams and fractured communication, which could become visible during participant handoff.

Similarly, there is **a danger to overemphasizing the importance of team member feedback.** While team members may have stellar ideas about clinics or messaging, the site lead, the clinic staff, and the NIH will ultimately determine whether these ideas should move forward: Do they comply with IRB guidelines? Can they be practically implemented? What is the burden on participants and clinic partners? Does this verge on coercion? In cases where site leads actively engage their teams in problem-solving, it is important that the leads make clear the line between an idea and what is actually implementable. Explaining the rationale for these decisions can also facilitate trust and support from team members.

Metrics for Building and Nurturing Teams

Keeping track of the engagement team structures (sizes, composition, longevity) and staff backgrounds and strengths could be important metrics of the team process. Although the effectiveness of engagement teams will be ultimately judged by the “the enrollment numbers” (RMC G), our interviewees raised concerns about using quotas to judge the engagement teams. As an interviewee noted (RMC D):

From a coordinator perspective, sometimes [just] tracking numbers [of recruited participants] can be dangerous because then you have people who are only going after the numbers and cutting corners to meet their metrics. And I say that having come from a clinical background, I’ve seen other clinical research facilities where people are so focused on the numbers and people will say: “Well, what are you doing to get those numbers?” And we’ve done site visits. How is it that this site in [random location] is blowing that study up and we’re struggling? And then you get there and find out they’re not fully—they’re not consenting people the way that you really should.

Similarly, RMC B was wary of setting a daily enrollment goal because “people cut corners to hit numbers.” Instead, this site had check-ins throughout the day to see how enrollment activities were going.

Instead of using individual or team enrollment targets, RMCs may want to **keep track of staff feedback about what works and what does not**. In addition to keeping good minutes during regular staff meetings to document staff concerns and actions taken to resolve them, documenting frequently asked questions about the AoURP that are addressed in the recruitment materials can help train new engagement staff.

Another way to measure team processes is to **conduct a process evaluation**. For example, RMC B had recently hired a team member with expertise in tracking and evaluating NIH-funded research. This team member and her research assistants were interviewing engagement staff to assess how well things were working:

They’re doing sort of this round robin. They select a different team member—sometimes leadership, sometimes people on the front line—and they’re doing qualitative interviews with them about things that need to change and what’s working and what isn’t working. And so there’s a growing collation of those sorts of comments as well.

Similarly, assessing team functioning (measures of how well the team works together) at different points in time can help provide insight into such factors as morale, attitudes, and issues that could impact sustainability of the initiative, like partnerships between stakeholders.

Finally, engagement leads can consider testing the relative values of the concierge and specialized models of team staffing. For example, in comparing each version, leads can track enrollment times (from first contact to biospecimen collection) and rates (enrolled versus contacted). Additionally, there may be team satisfaction implications to different models. For example, staff who feel better about their jobs because they are performing tasks more aligned to

their personal strengths (e.g., more comfortable with consent than with initial engagement) might be more satisfied than their colleagues who are asked to perform a full range of engagement activities.

8. Dealing with Uncertainty

The ways in which the AoURP staff deal with uncertainty strongly shape the process of engagement because of the pervasive and varying kinds of uncertainty that arise in the AoURP. First, the AoURP is a quickly evolving initiative with multiple moving parts, and changes and revisions to the protocol are to be expected. Second, some details of the AoURP are *as of now* undetermined, such as whether and which participants may be contacted in the future for participation in research projects that require collection of new data or what information or results will be given back to participants. Finally, many other aspects of the AoURP are unknown at this time—most notably, the research findings and clinical impacts that will result. RMC engagement leads suggested two main strategies that may help plan for an uncertain future: preparing to talk about uncertainties and adopting a continuous quality improvement mindset.

The literature recognizes that the uncertainty associated with enrollment in a new research field like genomics poses particular challenges,⁴⁸ but it does not offer many concrete recommendations for how these challenges may be addressed effectively. Enrollment procedures cannot include a full discussion of risks of the research projects that will use participants' data because the uses of those data are not yet known.³⁴ Moreover, participants cannot be briefed about what precisely will be learned from their data, and it is possible that they will learn too late that their data were used for purposes they find inappropriate. In addition, participants may not be able to fully consider how they prefer results to be returned to them if the possibilities have not yet been defined. Communications around areas of uncertainty have important implications for trust-building, decisionmaking, and retention.

The field of health communication usually posits that being open about uncertainties may enhance trust and credibility in a project, though few empirical studies of public trust and communication of risk uncertainty in the health care context have been conducted.^{49,50} Moreover, the literature on participant recruitment suggests that adopting a problem-solving mindset to address recruitment challenges in large studies may be helpful for reaching enrollment targets. As stated in the Institute for Healthcare Improvement's Model for Improvement, adopting a problem-solving mindset can help engagement teams continuously improve the quality of their outreach and enrollment activities by specifying an improvement goal, identifying metrics that should be tracked to evaluate progress toward achieving this goal, and developing specific changes in work processes that are needed to reach the desired goal.

Table 8.1 summarizes the strategies and tactics that RMCs used to deal with uncertainty. It also lists the purpose of each tactic and the conditions under which it may be effective. While there is some general support in the literature for the two engagement strategies discussed in this chapter, this facet of engagement offers unique engagement challenges for RMCs.

Table 8.1. Dealing with Uncertainty

Strategies and Tactics	Purpose	Potential Conditions for Effectiveness
Be Prepared to Talk About Uncertainties		
Become comfortable saying “we do not know yet.”	<ul style="list-style-type: none"> • Avoid deception and misunderstanding. • Avoid setting unrealistic expectations. • Increase participant understanding of the AoURP. • Increase transparency about what is known and unknown. 	<ul style="list-style-type: none"> • Enrollment has not been completed. • Relationship with participant is strong. • Setting is unhurried and not time-limited.
Focus on shared goals rather than on uncertainties.	<ul style="list-style-type: none"> • Explain the AoURP to large and diverse groups with different interests and concerns. • Increase awareness of shared goals. • Increase transparency about what is known and unknown. 	<ul style="list-style-type: none"> • Opportunities for follow-up will be available later. • Coercion to participate can be minimized.
Train staff to answer questions from participants.	<ul style="list-style-type: none"> • Increase engagement staff readiness and resilience. • Increase engagement staff knowledge about the AoURP. 	<ul style="list-style-type: none"> • Sites have highly diverse engagement teams.
Adopt a Continuous Quality Improvement Mindset		
Shift messaging as needed.	<ul style="list-style-type: none"> • Continually improve engagement efficiency and effectiveness. 	<ul style="list-style-type: none"> • A tactic is not resonating with particular participants or communities. • Enrollment numbers are not high.
Modify tactics to ensure engagement effectiveness.	<ul style="list-style-type: none"> • Continually improve engagement efficiency and effectiveness. 	<ul style="list-style-type: none"> • A tactic is not working as expected. • Strategies or goals have changed. • Enrollment numbers are not high.

Be Prepared to Talk About Uncertainties

Being prepared to have a conversation about the aspects of the study that have yet to be finalized is one of the most important strategies for dealing with uncertainties. Choosing a stance of openness about uncertainties and moving away from unknowns in order to focus on shared goals have both been used by RMCs. Most sites implement training approaches that help to prepare staff for communicating about uncertainty. Training to assist staff in clarifying ambiguous responses, addressing possible sources of bias, and redirecting patient interest have been cited in literature as helpful for clinical trial recruitment.¹⁶

Become Comfortable Saying “We Do Not Know Yet”

One tactic that can help when talking about uncertainties is to be open if one does not know an answer to a given question. Because engagement staff will be asked questions to which they do not have an answer, many RMCs intentionally train them on how to handle such questions. RMC engagement staff members should understand that it is OK to say, “We do not know yet.” RMC staff came up with a range of other similar phrases—“I can’t answer that now,” “The project is still working on that issue,” “I wish I knew the answer, but I don’t”—that would convey uncertainty honestly, accurately, and nondefensively.

Moreover, being comfortable with uncertainty also requires **correcting participant misunderstandings, even when areas of uncertainty remain**. At one site, AoURP staff addressed a participant question about return of results (“When will I get my blood tests back?”) by correcting the participant’s misconception that the study would definitely provide diagnostic results. The staff member had to be explicit that the AoURP could not yet specify the types of results that would be returned. An RMC B engagement staff member noted that it is important to avoid making promises when you actually do not know the answer to a question. If you make promises inappropriately, you may be viewed as breaking them in the future. Another engagement staff member at the same RMC agreed that “really being transparent about [using samples for future research but not knowing what that research will be] is really important. . . . Letting people know that so that they don’t feel like you’re tricking them into that . . . has been really important.”

Analogies or metaphors can help staff and participants come to terms with what cannot be known. For instance, RMC C staff reported sometimes struggling to respond to questions from clinicians about the AoURP. One engagement lead noted that clinicians had expressed concern that the AoURP lacked clear research questions. The lead responded that the AoURP is like “building a library” rather than just “a book.” It may be unclear how the volumes in the library will get used, but there is the potential for great value from use of the library. Instead of speculating about future research questions, the lead used a succinct analogy to acknowledge and normalize the level of uncertainty.

Focus on Shared Goals Rather Than Uncertainties

Some RMCs suggested not emphasizing the fact that certain aspects of the AoURP remain uncertain at this time selectively and focusing instead on what is known and shared rather than what has not yet been decided. This has some similarities to an approach called *strategic ambiguity*. Strategic ambiguity “enables different constituents to attribute different meanings to the same goal, or for powerful actors to construct different meanings for any given goal according to the interests of their audience”⁵¹ (p. 221). This means that two people may interpret the same situation differently, but they can still agree because the goals in the situation are ones that both parties can embrace in order to reach consensus. Taking a strategic ambiguity approach

can mean encouraging multiple viewpoints about abstract concepts or goals to allow for greater creativity and to preserve diverse views while promoting agreement, even as some details are not yet known.

At one site at RMC C, a staff member said that when asked about what a participant would get back, she responded, “You will get your results eventually.” However, she was somewhat uneasy that this response could function as a promise that could then be broken. Similarly, other RMC staff found themselves wanting to give vague answers (e.g., “You’ll hear from someone about that soon”) but then reminded themselves to be careful not to respond in ways that could be interpreted inaccurately.

A better response would involve **transparency about what is known and unknown at a given time and a refocus on shared goals or concepts**. For instance, at one site, community members expressed fears about receiving certain types of results, and the RMC staff member conceded that she was unable to address those fears in any detail. However, the staff member instead reverted to sharing personal stories related to precision medicine and health.

Focusing on shared goals rather than on uncertainty allows engagement staff to move away from questions where less is known and toward topics where both parties are in agreement. For instance, RMC staff found that they sometimes tried to respond with general information to questions with no known answers. However, if the participant is seeking more rather than less specificity, this approach can backfire. One RMC engagement team member was asked by a participant what results would be returned to her. The staff member described the kinds of results that participants may receive in the future, aiming to interest the participant in the range of possibilities, but then realized that the participant felt very strongly that she did not want certain types of results. The staff member was unable to reassure her about this concern. Instead, the staff member could have refocused the conversation around the importance of choice and input regarding health research and the ways that the AoURP was working on ways to offer participants options for receiving results.

Train Staff to Answer Questions from Participants

As an RMC E engagement lead put it, “When you’re doing a project that is so uncertain, building as much safety and structure as possible is very important.” Explicit **staff training and coaching on fielding questions when significant uncertainty remains** is one tactic for ensuring structure and safety. Sharing effective language, phrasings, and analogies and observing and giving feedback to staff members may help staff be comfortable saying “we do not know yet” or using inexact communication responsibly.

Several RMCs used trainings to prepare staff. As recommended in the literature,⁵² some sites used cultural competency training to achieve this and other goals. RMC D, for example, conducted communication workshops for staff that included improvisational comedy (improv) training. Improv training focuses on communication in unpredictable social situations. Improv skills entail building on others’ ideas (e.g., saying “Yes, and . . .”) rather than stopping ideas

short (“Yes, but . . .”). The engagement lead said that this training was effective to “help train our aides to be a bit more flexible in the way that they deliver the [AoURP] message.”

RMC staff can keep track of areas of uncertainty and concern together with the central AoURP program staff. Some RMCs reported drawing on current lists of frequently asked questions from the AoURP and keeping tabs on updates to the website and procedures. They also kept logs of the concerns and questions, such as the data that patients and clinicians would eventually receive and what this process would look like. At some sites, engagement leads did not shy away from discussing areas of uncertainty with their staff, directing their questions to the central AoURP staff, and cataloguing need-to-know information. Team dialogue about these open questions can increase comfort in encounters with participants.

Adopt a Continuous Quality Improvement Mindset

Adopting a flexible and adaptable attitude and management style can also be a successful strategy for dealing with uncertainty in the AoURP context. We consider this flexible and adaptable attitude and management style to be consistent with a continuous quality improvement (CQI) mindset. The RMC D engagement lead concurred with this assessment, telling us that overseeing the AoURP “is about a kind of continuous quality improvement. . . . It can take time to build relationships, and so something may take a bit of time to yield. So I think we’ll just have to be sure that we employ a variety of short-term as well as longer-term strategies, and keep the long game in view as we do.” Because there are continual or frequent changes built into the AoURP, fostering a CQI mindset is a way of framing these uncertainties as opportunities for improving work processes over time.

CQI entails a set of practices by which all members of a team continually ask how they are doing, whether they could do better, and how their processes could be refined. CQI includes an assessment of how well a strategy is working and to what extent that strategy is impacting project goals. Armed with the answers to these questions, team members implement new strategies to attempt to generate improvement. This also means being able to be flexible with tactics to better support strategies over time. Many tactics are part of the CQI approach adopted in the AoURP.

Shift Messaging as Needed

In addition to tailoring their messages, **sites refined their messaging to match the concerns of participants and communities.** As an RMC D engagement lead said, “We’re open to changing the messaging constantly if we find things that tend to resonate better with people.” Many RMC staff and engagement leads have ongoing discussions about how to improve language and messaging. For instance, some staff said they were pleased with the study title change from “Precision Medicine Initiative” to “All of Us.” As one RMC B engagement staff member said, “All of Us” “is catchy. It’s easy to recruit everyone. Every and any person should

be involved.” In contrast, this staff member thought that “Precision Medicine Initiative” was “not intuitive” and “required a lot of explanation.” She continued, “They say we should aim for an 8th-grade comprehension level. None of those words are easy to understand at that level.”

In another example, an RMC E engagement lead said that the team found that the “One in a Million” message undermined the “All of Us” message and chose not to use “One in a Million”-branded promotional materials in some of the RMC’s sites. The engagement lead explained that, while “One in a Million” emphasized an individual participant’s uniqueness, “All of Us” held participants together with an idea of a shared identity and shared purpose, a message that felt more culturally consonant and inspiring. In this way, individual sites learned over time which messages resonated well in their context and with the staff who use them.

Modify Tactics to Ensure Engagement Effectiveness

RMCs may need to **be flexible and periodically adjust their engagement tactics to ensure engagement effectiveness**. For instance, the RMC E engagement lead said that a small tweak to the AoURP brochures increased engagement at table events. After tracking the number of people coming to their tables, they saw that after they put an IRB-approved sticker on their brochures that said “\$25,” table traffic increased. At RMC B, the AoURP staff initially went on rounds with physicians to identify potential enrollees. But staff realized that the nurses often had more-helpful information and were able to help direct the AoURP staff toward or away from patients, for example, by not introducing staff to patients who were too ill or about to undergo a procedure. At another RMC E site, the AoURP team shifted their working hours to 1–9 p.m. in order to more successfully telephone people after work. An interviewee stated that, “People are busy. And they’re not going to interrupt work to take a call. You have to catch them after work.” Additionally, at this same site, wait times in clinics were so low that they decided to deemphasize recruitment in waiting rooms and recognized that potential participants would prefer to come for a scheduled appointment.

Sometimes, **changes to the hiring approaches may be useful**. RMC engagement leads learned over time about the kinds of attributes and experiences that made staff effective in the AoURP, and they consequently began to look for new types of people to hire. The RMC B engagement lead described a growing awareness on the team that the types of people the RMC was hiring into engagement teams needed to shift. Another engagement lead decided to stop looking for clinical skills or research experience in her hiring: “[W]e’re looking a little bit more for the attitude because I think our philosophy is that the skills can be taught and the attitudes cannot” (RMC E). Relatedly, another site at the same RMC recruited a phlebotomist who was initially unaffiliated with the AoURP but was very popular with patients to help with AoURP blood draws at the site.

Unintended Consequences of Dealing with Uncertainty

RMC engagement staff should be cautious in their use of strategic ambiguity and never focus on shared goals at the expense of transparency. There are ethical considerations in terms of when ambiguity can help achieve collective action (e.g., move a group of people closer to a common goal) versus when it can lead to misunderstanding or come across as deceptive. The qualities that makes the concept of strategic ambiguity useful also have downsides. For example, strategic ambiguity can better allow for deniability than very clear communication, meaning that receivers of a message may interpret a conversation in a way that can be denied by the sender of the message. Misunderstandings or conflicts can undermine the credibility of the AoURP. For example, word of mouth is important in many locations for engagement with local communities. If a participant communicates the wrong information to friends and families, this may cause confusion.

The **uncertainty associated with genomic studies has ethical implications for consent, risk assessment, and return of results that require sophisticated ethical oversight by IRBs.** Given the newness of the issues, it may help for engagement leads and staff to have opportunities to review (including in discussion with IRB members) the ethical principles and challenges underlying decisions about consent and communication of risk. Relatedly, refining messaging as needed to facilitate communication may mean that participants enrolled at different sites or RMCs receive slightly different information or impressions of the AoURP. This can lessen the feeling of shared purpose and could lead to misunderstandings.

Finally, **trial and error—such as is required in a CQI model—is labor-intensive and may be inefficient in a fast-changing environment.** It requires that staff devote time and resources to gathering real-time tracking data, brainstorming new solutions, strategizing their implementation, and then tracking again to evaluate whether goals have been achieved. Innovative choices, such as to hire new kinds of research staff, are both high risk and high reward.

Metrics for Dealing with Uncertainty

Conversations with interviewees touched upon dealing with uncertainty only indirectly. For instance, **metrics for laying the foundation, tailoring communications, and building and nurturing teams may also be helpful for measuring tactics used in dealing with uncertainty.** Measurement is a key component of CQI. Identifying aspects of engagement that may not be working and therefore should be changed requires knowing that they are not effective. Indeed, metrics can allow sites to assess the degree to which certain tactics are working as intended and whether changing a tactic has resulted in improved performance. For instance, in the case of RMC E adding stickers to brochures, without their tracking procedures for handing out fliers at events, they would not have been able to assess whether the sticker had made an impact.

RMCs should systematically catalog and **track questions raised by potential participants** and topics about which potential participants need more information. By collating these questions, teams can develop accurate and consistent responses for potential participants. In parallel, **RMCs can implement A/B testing to track the effectiveness of different responses to these questions**. While there is a range of factors that will determine whether any individual enrolls in the program, by focusing messaging and tracking the consequences, engagement teams can consider whether there are larger patterns to engagement and refusals.

Additionally, **RMCs can track the effectiveness of different training techniques when it comes to finalizing enrollment with a potential participant**. For example, RMC D, which trains its teams using improv techniques, might find that its enrollment rates were higher because staff were comfortable with and capable of handling unfamiliar and unexpected questions.

Finally, **keeping track of why certain hiring decisions have been made** may be necessary for evaluating the effectiveness of having engagement staff with certain skills or experiences. For example, teams with deep medical training, such as those at an RMC E site, may find that these engagement specialists have higher success rates because they can better explain the uncertainty and possibilities in the science.

9. Markers of Engagement Success

A key characteristic of a best practice is its effectiveness in reaching a desired outcome. The immediate goal of engagement in the AoURP is full enrollment of at least a million participants with diverse backgrounds. Many questions remain about how to drive enrollment numbers up. The AoURP engagement staff want to know more about what motivates people to enroll, what questions or concerns about the study are most critical, and what factors turn potential participants away. Answers to these questions may help RMCs improve the effectiveness of their engagement efforts (e.g., the number of fully enrolled participants).

Several of our interviewees noted the importance of keeping track of factors to help clarify what drives up enrollment numbers and what keeps people from withdrawing from the study. Doing so requires knowing the number of participants who (1) were informed about the study, (2) expressed an interest in the study, (3) started the enrollment process, (4) fully completed the enrollment process, and (5) stayed engaged with the study over a period of time. RMC representatives noted that tracking “conversion rate,” or the number of fully enrolled participants relative to the number of people exposed to a particular engagement strategy, is a key measure of effectiveness. While some of these metrics are difficult to collect (e.g., the number of people who have been informed about the AoURP), RMC staff saw them as critical and expressed a belief that “the ultimate measure of our success is recruitment” (RMC I).

Nonetheless, RMC staff also suggested a more comprehensive view of engagement success. They emphasized that the AoURP was accomplishing many additional goals. In fact, many RMC staff considered these additional markers of the AoURP success to be as important as meeting enrollment numbers, and many hoped to log and track these successes over time. These markers may reflect benefits for enrolled participants, stakeholders, biomedical research, health, or society generally. Although the AoURP may not have been designed with all of these benefits in mind, the initiative is likely to generate a number of positive outcomes. In this chapter, we describe the most common markers of success (beyond enrollment) mentioned by engagement leads and staff.

Increased Trust

Trust was, by far, the most frequently mentioned benefit of the AoURP. One of the goals of this initiative is to engage underrepresented populations who have not been actively involved in research in the past. Successful engagement could help overcome the legacy of distrust in research and researchers. “Research studies in the past,” as one engagement staff member explained, “[are] a touchy subject with American Indian and American Native communities. We want to make sure that this is done properly and they have the educational resources in hand and

understand the mission of the program prior to going out and actively seeking their enrollment” (RMC B).

Beside overcoming the negative legacy of distrust, **RMCs are trying to increase participants’ levels of trust in research, science, academic and research institutions, and medical facilities.** As one engagement lead put it,

We very much view this as an opportunity to increase the trust and the awareness that people, especially in the more diverse neighborhoods that we serve, have in our institutions, and sort of increase their knowledge about how important it is for them to participate in research studies well beyond All of Us. We have hundreds of research studies that are going on all the time . . . and we see this as an opportunity to really, really build their trust in us as organizations that are there to care for them and involve them in these activities (RMC D).

One of the engagement leads we interviewed noted that trust has to be measured at the national level, not at the RMC level:

I think trust is an outcome of people’s participation with a national program. Part of the trust that we’re leveraging is that they already have some trust in their local hospital and that’s why they joined it in the first place. I know from our research . . . that trust in federal organizations is quite low. People trust federal agencies at the same level as they trust for-profit health plans. That’s pretty low. I think measuring trust of the enrolled participants in All of Us, measuring trust in NIH, and measuring trust in the research being done in All of Us So it’s trust in the purpose of the research as well as trust in the agencies conducting it. I think that’ll be critical (RMC A).

Improved Public Perception of Research

One RMC goal is **to change the public perception of research by making research more useful to communities and giving it a more human face.** As one engagement lead explained the advantage of the AoURP:

[I]s the research providing value to my community, to the people who need it? Because with a million participants, we actually have an opportunity to change the public perception, and so I think the biggest thing that we could measure is whether we’ve actually done that (RMC A).

By engaging in a conversation with potential participants, engagement staff are signaling that participation of every individual is valued and that the study is treating each participant’s information as a special gift that is greatly appreciated. By stressing that each potential participant is “special,” the AoURP may change the perception of research and researchers, which may increase participants’ willingness to participate in other studies.

By trying to change how individuals participate in research, **the AoURP may redefine the process of conducting research**, from participant enrollment to dissemination of study findings, **to make research more attractive and engaging to participants.** At this point, RMCs are focused primarily on enrollment efforts: “What goes into presenting the research program to a

participant or potential participant so that you make the best possible outcome. . . . We are trying to change the whole . . . research and the interaction between participant and study, [to do it] in a new way. And I think this is really exciting for me, personally, to see this approach and interaction” (RMC C).

Increased Participation in Biomedical Research

If implemented right, the AoURP has the potential to **restore health equity in the conduct of biomedical research:**

All of Us is truly an opportunity to right some wrongs, but we need to be a good partner in this process. . . . We’ve had years of research that have purposely or unintentionally violated people’s rights, cut people out. . . . As a country, we have a long history of not doing this right. In All of Us, we need to show we can be trusted partners, and to account for biases toward European Americans. This contributes to health disparities because we have more knowledge for one group than another (RMC E).

By addressing the legacy of distrust in research among racial and ethnic minorities, the AoURP may increase a **sense of pride about their research participation** and ultimately help promote future participation in biomedical research among underrepresented groups. Explains an RMC G engagement lead: “I think they felt so ignored, so it’s almost a source of pride [to be invited to participate]. ‘Oh, wow, you want to know about me?’”

Once participants get excited about research, they may become **more interested in participating in other research projects and clinical trials that are specific to their health conditions:**

We think that there’ll be a lot of downstream benefit. Once you get people who are healthy or don’t have a specific disease that we’re trying to recruit for to participate, we feel like we could get communities to join, be more open to participating in clinical trials that are maybe cancer-focused or disease-focused. And we hope that this changes the culture to allow people to have this conversation and not feel so threatened (RMC A).

Moreover, by engaging participants in research design, the AoURP may increase **community capacity for conducting research:**

What I see now is a deeper engagement of participants in research, more as partners with researchers in a truer sense of really bringing them on even before you do the research. To have them inform hypothesis development or the development of the research questions to educate them about method, so that they can help you think through sampling issues for vulnerable populations, as one example. To bring them on to even discussing analyses and results and how do we interpret and disseminate and implement those results. So it’s a really deeper, more contemporary view of engagement (RMC H).

Increased Scientific Literacy

Participant and community engagement are core values of the AoURP. By shaping how the initiative is designed and implemented and which research projects are conducted using the AoURP data, both community members who are actively involved with the initiative and participants who will have access to their data and the results of the studies that used them may benefit from an increase in their levels of scientific literacy. Indeed, RMCs are investing in “educating the population about research, about the questions to ask, about how to be an informed consumer” (RMC F). As another interviewee put it, “The biggest return that you can do to a community is education. You have to educate them” (RMC B).

Sharing the results of the studies that used a given participant’s data with the participant may **increase overall scientific literacy and demand for evidence-based information**: “Having a forum for bidirectional exchange” that is broader than the results of one study can help increase overall interest in science and make citizens informed consumers of research (RMC D).

Increased Awareness of Precision Medicine

The concept of precision medicine is relatively new and unfamiliar not only to many potential participants, but also to clinicians. Consistently presenting the AoURP as a precision medicine initiative may **increase public and clinician awareness of precision medicine and precision health**. As one of the engagement leads we interviewed explained: “We really believe that we need to have a precision-medicine–informed community, just like the CTSI [Clinical and Translational Science Institute] in general is a research-informed community. So really educating people about why it’s important. It’s really telling them what to look for in their own health care and in the future” (RMC F).

Because the AoURP is currently planning to return some results to participants, including yet-to-be-determined elements of their genetic testing results, RMCs are engaging clinicians in an attempt to prepare them for the kinds of questions that their patients who participate in the AoURP are likely to ask them. Therefore, another outcome of this initiative might be increased awareness and understanding of precision medicine among clinicians. Explains an RMC F engagement lead: “We are doing a lot with physicians in particular because many of them are just terrified about getting this genetic information and not knowing what to do with it. So I think that’s a huge benefit, regardless of whether it’s a million people or not.”

Strengthened Relationships

One of the outcomes of the AoURP may be **improved collaboration between various institutions**, such as between academic medical centers that make up an RMC or between community providers and academic medical centers. In addition to these cross-institutional relationships, RMC staff described the AoURP as resulting in improved collaborations within

institutions, such as among disparate research centers (e.g., Clinical and Translational Science Institutes) and academic departments. An RMC E engagement lead explained that his or her institution had a long-standing partnership with a community hospital, but they had stopped collaborating about a decade ago. As a result, doctors at that community hospital were not involved in research projects. By reestablishing this partnership as part of the AoURP, RMC E hoped to increase community doctors' capacity for research and rebuild trust in academic research institutions in the neighborhood. At another RMC, sites that were accustomed to competing with one another for research dollars, trainees, and patients committed to viewing enrollment for the AoURP as a unified RMC goal to encourage a sense of partnership rather than rivalry. In addition, two sites whose training collaboration had been severed in the past decade used the AoURP to reestablish research ties.

All RMCs we interviewed are building on the existing relationships between academic institutions and community organizations. By working on such a big and complex project together, **RMCs are expecting to further strengthen their existing relationships and build new relationships within communities.** One participant noted that the process of relationship-building assumes that all parties keep their promises. For the AoURP, the ultimate promise is not necessarily to enroll a million participants, but rather to conduct the AoURP in a way that would strengthen the medical center's bonds with the community and set the stage for future progress together. As an RMC B engagement lead said, "Success for me, even if hypothetically we couldn't get to the million . . . would be really doing something with whatever it is that we get and coming through with all the promises. We're going to do everything that we can to protect these data. We are going to build these relationships with communities. We're going to do things in the right way."

Narrowing the Digital Divide

Finally, the AoURP is encouraging digital engagement as a way to ensure successful enrollment and retention of a million participants. The RMCs, however, are encountering a substantial number of potential participants who do not have email accounts. In some sites, 60 to 70 percent of potential participants do not have personal email addresses (RMC C). Moreover, many participants have never used iPads and do not know how to scroll using their fingers. Because engagement staff at these sites help potential participants create email accounts and offer one-on-one assistance with using tablets, **the AoURP may increase computer literacy among underrepresented communities and help narrow the digital divide.** While one-time assistance may not be enough to make such participants fully comfortable with using technology, a brief one-on-one help session may increase their comfort level enough to encourage them to seek additional training.

10. Three Key Recommendations for Participant and Stakeholder Engagement

In this final chapter, we recommend three types of activities that all RMCs should consider pursuing in the course of the AoURP. These recommended activities will build on and strengthen patient and stakeholder engagement at all sites, improving enrollment, enhancing the credibility and trustworthiness of the AoURP, and bolstering support within communities for the AoURP. In addition, these activities will improve the field's understanding of engagement as a whole and will answer important questions about how to engage individuals from diverse backgrounds in research. Although our recommendations are intended to enhance engagement within the AoURP, we also highlight important lessons learned that may be useful to precision medicine researchers in general.

These three recommendations are presented in Table 10.1. First, we describe six critical best practices, one for each facet of engagement, that represent the most important strategies for engagement success. We describe strategies that may improve implementation of these practices in all settings. Second, we outline key aspects of an approach for evaluating engagement success, including the importance of tracking markers of engagement success, and propose a series of research questions that can be addressed through systematic data collection. In particular, we emphasize that many of the engagement questions that the RMC engagement leads and staff debate in real time while in the field include a set of important empirical questions whose answers will be significant to the broader research community. We further recommend that RMCs or the AoURP as a whole find ways to gather systematic data to address some of these questions. Finally, we discuss one gap we identified in engagement practices: how to retain enrolled participants over the course of the AoURP. We recommend that RMCs incorporate retention strategies in a thoughtful manner that includes coordination with the retention efforts spearheaded by the national AoURP office.

Table 10.1. AoURP Patient and Stakeholder Engagement To-Do List

Recommendation	Recommended Strategy
Implement Best Practices	<ul style="list-style-type: none"> • Expand existing community partnerships. • Foster a spectrum of leadership support. • Engage a mix of study champions. • Make precision medicine relevant to participant priorities. • Build an engagement team with diverse expertise. • Be prepared to talk about uncertainties.
Evaluate Engagement Success	<ul style="list-style-type: none"> • Use the three Ms of engagement framework. • Catalog and evaluate possible mechanisms of engagement success.
Incorporate Retention Strategies	<ul style="list-style-type: none"> • Minimize the perceived burden of follow-up requests. • Proactively manage the samples for future projects. • Manage the database with participants' contact information. • Build relationships and stress the longitudinal nature of the project. • Maintain regular contact with participants to minimize attrition. • Tailor and personalize messages.

Implement Best Practices for Engagement

Our report describes an array of engagement best practices, strategies, and tactics likely to yield success in the AoURP. Based on these data, we can recommend an abbreviated “to-do list” of six engagement best practices that each RMC should consider implementing. As described above, we recommend tailoring each engagement tactic to the RMC and site context by integrating feedback from participants and stakeholders, through trial and error, and as the nature of the engagement challenges shifts. We note that there may be some tactics that can help implement more than one strategy or address more than one engagement goal, such as training staff, soliciting community feedback, using physicians as AoURP champions, and tailoring the AoURP message. We anticipate that the recommended best practices for engagement we describe below would also promote success in studies similar to the AoURP, such as large-scale biobanking studies, patient registry studies, and genomic research studies.

1. Expand Existing Community Partnerships

Laying the foundation for communities entails building awareness of precision medicine and preparing community members for considering enrollment in the AoURP. RMCs can use several tactics to pursue this goal—e.g., linking current, community-salient events to precision medicine; using community-level data to design an outreach strategy; and establishing CABs and PABs to elicit input from them and other community stakeholders. These tactics not only help RMC engagement staff understand how the AoURP can suit community needs, but they also build

relationships of trust, respect, and mutual understanding that can facilitate next steps in the AoURP.

Implementing a study like the AoURP without involving and learning from communities would be unwise. Resulting study activities might be low-value and low-yield or may actively undermine and diminish community trust and interest in the AoURP. While the work of building and strengthening community relationships and community partnerships may seem time consuming, these investments in partnerships pay dividends down the road in efficiency, study acceptability, and possibilities for open dialogue when (not if) challenges arise.

RMCs that have expertise and experience with community partnering may be better prepared to work with communities in ways that will support the AoURP's success. Nonetheless, even RMC engagement leads or staff who are entirely new to partnering with community groups may benefit from building stronger relationships within the community. Building partnerships is not simple or intuitive, so RMC staff with less experience in community partnering should actively seek mentoring and support from others with more experience. And, because partnerships always need to be renewed and revised, the mentoring should be ongoing. The AoURP may need to ensure availability of some financial resources to support building strong relationships within communities at all of the AoURP sites.

2. Foster a Spectrum of Leadership Support

In any innovative endeavor, well-placed allies can make enormous contributions to the endeavor's success. In the AoURP, an effective engagement approach may begin with fostering a spectrum of leadership support by encouraging visible support from senior leaders, securing buy-in from clinical department leaders, and arranging protected time for RMC employees to participate in the AoURP. Each of these efforts to build support from the top will cascade throughout a health provider organization and encourage clinician and staff participation in the AoURP, clinician and staff championing of the AoURP, and positive word of mouth that will sustain enthusiasm for the AoURP.

Many factors may increase the readiness of leadership to support the AoURP, including the AoURP's perceived credibility and trustworthiness, the expertise of staff who conduct outreach, and the resources that the AoURP can bring to the RMC. The AoURP may dovetail with related efforts in the RMC, such as a parallel biobanking effort or an interest in innovating around precision medicine. It will fall to RMC staff to find these linkages and communicate with the leaders how the AoURP can be leveraged to support these other extant goals. RMCs will also need to keep in mind that, once granted by leadership, trust can be easily broken. Relationships of advocacy like these will need to be renewed and revised as priorities change. Relationship-building will need to be continuous if key leaders are to remain committed to the success of the AoURP.

3. Engaging a Mix of Study Champions

Study champions can include physicians, other clinical personnel, community members, and enrolled participants. Champions play several critical roles in the AoURP. They make enrollment successful by connecting AoURP staff with potential participants in settings and contexts in which potential participants are prepared to receive the message of the AoURP. Champions also provide a trusted, credible “face” for the AoURP that helps the study feel familiar and comfortable. And they help knit together a sense of continuity in a participant’s relationship with the AoURP. Each time a participant sees the champion for reasons unrelated to the AoURP (such as during the next doctor’s visit), the participant is reminded of his or her participation in this study. Champions can be present with participants at times and in contexts that the study staff cannot reach, and the champion’s presence can bolster the participant’s relationship with the AoURP in the process. Champions should be involved whenever possible. They should be fairly compensated for their time, such as with protected time, stipends, or substantive professional credit, so that they do not feel exploited or taken advantage of.

RMCs and sites may need to adjust a champion strategy to a context and integrate champions into the engagement team. As we noted, many sites began with one expectation about champions but quickly realized that other tactics were more consonant with their sites or were less intrusive. RMCs should consider offering a short, accessible orientation program to champions and gather data whenever possible about how well a champion strategy is working (e.g., number of enrollees tied to a champion, time invested by champion, participant perceptions of the champion strategy). RMCs and sites may want to consider how champions could help with retention, define a role for champions in the context of the national launch, and identify ways to thank champions for their contributions to sustain champions’ enthusiasm for the AoURP.

4. Make Precision Medicine Relevant to Participant Priorities

Precision medicine can be made relevant to participant priorities by presenting it as a tangible, comprehensible aspect of the real world. Analogies for precision medicine, such as prescription eyeglasses or insulin dosing, can be extremely helpful. But staff can also talk about the promise of targeting a treatment to an individual, of avoiding overtreatment by defining which drugs are needed and for whom, and of moving beyond inexact biological categories like race when designing treatments. Engagement staff might suggest that precision medicine could explain why some individuals are protected from common illnesses, making it possible to predict an individual’s prognosis with more exactitude. Teams could work together to review the analogies and potential future scenarios to share with potential participants during enrollment.

RMCs had considerable successes in tailoring and personalizing their messages to participants and communities; however, at most RMCs, these efforts focused on raising awareness and enrollment and not on retention. Likewise, many interviewees noted that they are expecting retention strategies to be developed and communicated from the national NIH level.

However, many engagement leads and staff were strongly motivated to tailor and personalize messages for participants that would support retention by sending thank-yous and birthday cards, emailing newsletters that share relevant information, and (ultimately) returning results that are comprehensible and consonant with participants' preferences for learning about themselves.

5. Build an Engagement Team with Diverse Expertise

To build an engagement team with diverse expertise, AoURP sites may consider hiring staff with marketing and sales experience who also understand community priorities and know the clinical sites where recruitment takes place. Many sites and RMCs hired staff with unique expertise that may not be available elsewhere. For instance, in an urban context, an RMC was able to hire engagement staff with foreign medical degrees who were awaiting medical training. These staff bring deep knowledge of precision medicine and (often) language skills. Engagement leads may want to consider using opportunities to hire staff who may be able to message the AoURP in a way that other team members cannot.

No single staff member will bring all necessary skills to the table, and engagement leads will likely learn from their staff members' experiences. Because the AoURP sites hire staff from different backgrounds, it can be challenging for all team members to immediately assume that other staff are appropriately prepared. Staff members may have biases in favor of their own backgrounds and need time to learn that others also bring strengths. Establishing and sustaining expectations that teams will engage in respectful collaboration and information-sharing are critical to team success. It may be effective for staff members to discuss their areas of expertise or personal backgrounds with their co-workers.

6. Be Prepared to Talk About Uncertainties

The AoURP is designed to evolve over time; consequently, RMCs must be prepared to address uncertainty about the future as a feature of both genomic and biobanking research in general⁴⁸ and the AoURP in particular. Indeed, the evolution of the AoURP might be framed as a strength: The AoURP is intended to be a learning context, both as participants and staff learn from their experiences and as the research advances. This expectation that RMCs and the study as a whole will learn over time entails particular responsibilities. RMCs need to recognize the critical importance of keeping track of and talking through with others (both locally and at the national level) those "open questions" and remaining areas of uncertainty so that as new decisions are made and as new facts are known, RMCs can immediately incorporate the new information in their work with participants and stakeholders. Relatedly, the channels of communication from the national project and between RMCs need to remain open to allow for timely information-sharing as new answers develop.

Consistently communicating about areas of uncertainty may help AoURP engagement leads and staff plan for the future. For instance, engagement leads are already anticipating potential future roadblocks and opportunities. More than one RMC noted that its enrollment efforts have

been successful to date by capturing the most accessible groups of participants (colloquially discussed as “low-hanging fruit”), including friends, family, employees, and patients. However, they are beginning to realize that they may need contingency plans to enroll new individuals who had been reluctant to join in a noncoercive manner or to access new populations for enrollment using an ethically appropriate strategy. Likewise, many RMCs are taking creative steps to localize enrollment efforts and will need to plan far ahead to obtain IRB approval for these local adaptations. Simultaneously, sites may want to consider discussing anticipated future problems (not just current difficulties), such as retention approaches, plans for returning results and preparing clinicians to speak to their patients about these results, and the challenges of having participants return for future studies, particularly in communities with a wide digital divide. These discussions may affect how the AoURP and RMCs plan for follow-up communication with participants and address potential challenges with a digitally focused retention strategy.

Evaluate Engagement Success

In addition to implementing these six best practices for engagement, each RMC should consider ways to systematically evaluate the process and outcomes of their engagement efforts. Gauging the effectiveness of an engagement strategy includes assessing performance and impact: Is the strategy accomplishing what you want it to accomplish? Is the strategy making an impact? Measuring *performance* means assessing the effectiveness of a practice or tactic. And *impact* means assessing whether these successful practices help an organization achieve its larger goals. RMCs may find it helpful to use Getting to Outcomes^{4,5} or a similar model in designing, implementing, and evaluating their engagement activities to determine whether engagement strategies and tactics meet their needs or whether any activities need to be modified to ensure engagement effectiveness.

Use the Three Ms of Engagement Framework

As outlined in our three Ms of engagement framework, evaluating engagement activities requires defining a set of possible and desired outcomes (markers), tracking features of engagement that might determine these outcomes (metrics), and identifying how a given engagement strategy should achieve the intended outcome (mechanisms). All RMCs should routinely catalog markers of engagement success that they feel matter in their contexts (e.g., building trust, narrowing the digital divide) and, with the help of the AoURP leadership, use metrics that can measure their efforts toward achieving these goals (e.g., use surveys to measure change in trust in the AoURP, science, and biomedical research among enrolled participants; identify the number of referrals through snowball sampling; count the number of new email addresses created). Conceivably, each site could determine a small number of engagement outcomes, and their related measures, and proceed to conduct their own evaluations. Or the study as a whole could determine which markers of success could be tracked at each RMC.

Catalog and Evaluate Possible Mechanisms of Engagement Success

The efforts to evaluate engagement success in the AoURP could yield important findings with high significance to multiple research fields. In selecting measures and outcomes to evaluate engagement success, the AoURP can test important hypotheses about how engagement in biomedical research can be improved. As shown in our three Ms of engagement framework, measures and outcomes are linked by mechanisms that describe the nature of the process of engagement. Many of these mechanisms are very poorly understood and, as such, constitute hypotheses about how engagement works and how it can be optimized.

Here we identify some key questions about how RMCs could achieve engagement success. We also highlight mechanisms that would be feasible to study in the AoURP and that fill an important gap in the literature on participant and stakeholder engagement.

Regarding the important goal of **improving research inclusion**, RMCs can examine (1) which engagement strategies and tactics increase the number of referrals through snowball sampling; (2) which engagement strategies and tactics are the key levers that lead individuals with no prior research experience to enroll in the AoURP; and (3) what tactics, framings, messages, and signage encourage enrollment among those who are new to research or who are initially skeptical, compared to those with prior research experience.

Regarding **the process of trust-building**, RMCs can examine (1) whose endorsements make the AoURP appear trustworthy, particularly to individuals in populations currently underrepresented in research; (2) which engagement strategies and tactics work better in different contexts for the purposes of building trust; (3) which messages or experiences in the study motivate an enrolled participant to recommend enrollment to his or her family and friends; and (4) to what extent transparency or uncertainty serves to undermine or bolster trust in the AoURP.

With respect to the goal of **explaining precision medicine** to participants and stakeholders, RMCs can explore (1) what content and media types (e.g., electronic, face to face, didactic sessions) increase scientific literacy in low-literacy individuals; (2) whether current (e.g., prescription eye glasses), cutting-edge (e.g., tailored chemotherapy regimens), or hypothetical examples (e.g., designing a personalized diabetes drug) of precision medicine generate the most enthusiasm; and (3) whether and under what circumstances enthusiasm in precision medicine translates into interest in AoURP enrollment.

Regarding the goal of **strengthening research relationships**, RMCs can examine (1) what kinds of resources, knowledge, and activities can be shared across institutions to build capacity for research; (2) the attributes, skills, and experiences that make an AoURP staff member ready to succeed in linking disparate institutions; and (3) the incentives and benefits that add value for different types of stakeholders (e.g., community providers, academic medical centers, community organizations) and support involvement in the AoURP.

Incorporate Retention Strategies

Throughout our ethnographic work, we identified one gap in the AoURP engagement practices to date: how to retain enrolled participants over the course of this initiative by building a strong connection with them and retaining their interest in the initiative in the long run. To fill this gap, we identified a series of best practices for retaining participants in longitudinal studies. We recommend that RMCs consider adapting these strategies and incorporate them into their engagement approaches. A first step would be for the national AoURP engagement team to establish clear expectations and procedures and communicate to all RMCs their responsibilities with regard to retention. Throughout this report, we described a small number of retention strategies (e.g., participant newsletter) used in the AoURP. However, many RMCs deferred retention tasks and invested their energies in awareness and enrollment. While they were interested in boosting retention approaches, staff at these RMCs were under the impression that the national program would manage all retention strategies.

Conversely, some RMCs thought that they could and should pursue retention strategies and directed resources to do so. These RMCs expected to alter their retention activities to accommodate national approaches when those come online, but they did not defer those activities that they could pursue. These differences among RMCs were partly shaped by the availability of study resources. Those RMCs that felt stretched with regard to funds or staff were more reluctant to take on retention tasks. These sites assumed that national efforts would come first and that their efforts would have the highest yield if implemented around them. Contrarily, those RMCs that had more flexibility with funding may have been able to experiment with retention, even while recognizing they may turn over some of these tasks to the national AoURP in time. Moreover, sites that have been enrolling participants for a longer period of time were more likely than those that had just recently started enrollment activities to strategize about participant retention.

Below we describe key findings from the literature on retention in longitudinal studies like the AoURP (see Table 10.2). Retaining participants in such studies is challenging because of nonresponse issues. Initial nonresponse can occur at the start of a study if a participant fails to respond; sample attrition, which is a form of nonresponse unique to longitudinal studies, can occur during the course of such studies due to participants dropping out. According to Laurie,³⁷ attrition usually stems from one of three reasons: geographical mobility (i.e., people move and can be hard to trace), failure to contact participants (e.g., because contact information changes or is not utilized), and refusal (i.e., a person declines to participate going forward).

Table 10.2. Literature-Endorsed Participant Retention Strategies and Tactics

Retention Strategy	Possible Tactics
Minimize the perceived burden of follow-up requests.	<ul style="list-style-type: none"> • Offer low-burden follow-up visits. • Provide monetary incentives. • Provide nonmonetary incentives (bus tokens, snacks).
Proactively manage the samples for future projects.	<ul style="list-style-type: none"> • Determine early who will be re-contacted. • Communicate clearly who will be re-contacted.
Manage the database with participants' contact information.	<ul style="list-style-type: none"> • Use systematic contact and scheduling procedures. • Make ongoing updates to contact database. • Allow participants to self-update contacts. • Log contact attempts and personalization strategies.
Build relationships and stress the longitudinal nature of the project.	<ul style="list-style-type: none"> • Maintain strong relationships with research team. • Include profiles of staff in updates. • Include a personal, persuasive cover letter.
Maintain regular contact with participants.	<ul style="list-style-type: none"> • Share study reminders and follow-up reports. • Be in touch without requests for additional data.
Tailor and personalize messages.	<ul style="list-style-type: none"> • Emphasize study benefits. • Use multimodal strategies (text, email) suited to population.

While some amount of attrition is likely in any long-term study, steps should be taken to minimize attrition. Attrition is problematic due to the loss of potential data that can contribute to nonresponse bias, in which participants with certain types of characteristics drop out at a higher rate than others, potentially biasing the results. To reduce attrition rates, engagement staff should **minimize the perceived burden of follow-up requests** to participants. Frequent requests for contributions (e.g., taking a survey, doing an interview, contributing a biospecimen, etc.) can lead to “panel fatigue.”³⁷ The cost of one’s time is often the biggest hurdle to participation in longitudinal studies; therefore, incentives can be used to offset that burden.^{17,37,53} The use of monetary and nonmonetary incentives may make participation in future studies that require additional data collection more appealing to already-enrolled participants.^{17,53} Additional study design factors that may affect potential willingness to participate, attrition, and nonresponse include the length of time required for participation, the complexity of a task, or the amount of work involved in participating (e.g., a too-complex survey); the perceived salience of a topic (whether people believe that subsequent waves of data collection are relevant to them, to loved ones, or to a community); and participants’ experiences in the existing study (e.g., a negative enrollment experience may lead to dropout). Additionally, the mode of data collection can impact attrition; for example, in-person interactions in participants’ homes usually have higher response rates than phone or online surveys.³⁷

In addition, study design decisions that include **proactive sample management** can improve retention. Sample management means deciding on the sampling approach for future studies. These decisions need to include approaches to potential nonresponse and requests for more

data.³⁷ For example, how much follow-up will occur when respondents fail to respond to a request? Is it possible to determine reasons for nonresponse (refusal to participate, incorrect contact information, other reasons), and how will reasons be tracked? At what point should requests for more data stop when participants do not respond? How do researchers handle situational nonresponse, when a participant cannot participate at a given time but can potentially participate in the future? These types of questions should be answered early in the study so that participants receive clear and consistent communication about their expected involvement in the study and are able to make a fully informed decision when they consent to participate in a follow-up project.

Managing the database with participants' contact information is critical for retention. The minimum information needed is the participant's full name and email address. It is helpful to request as much contact information as reasonably possible, including one or more telephone numbers. Additionally, it can be helpful to request the information of at least one other contact for the participant, along with details about that contact's relationship to the participant. It is also good practice to provide participants with an easy way to update and maintain their own contact information. A complete database should include logs of all contact attempts, as well as notes that include suggestions for future contact or notes about approaching the participant effectively (e.g., that a participant would prefer to hear from a female staff member).¹⁶ Maintaining a contact database that is continually updated should be considered a mission-critical task for teams managing longitudinal research.

When communicating with participants, engagement staff may want to consider the following three strategies that can help minimize attrition.

First, **building relationships and stressing the longitudinal nature of the project** may encourage retention. Smith et al.⁵⁴ describe the importance of prepping participant mindsets from the outset and forming positive alliances with participants to normalize the idea that the study will be a longitudinal commitment. Meneses et al.⁵⁵ analyzed retention in longitudinal studies of breast cancer survivors and found that the strongest predictors of retention were intensive follow-up and continued contact, social support, flexible schedules, feelings of trust and support for the study, and self-motivation and altruism on the part of participants.

Second, **communicating regularly with participants** may improve retention. Wilke et al.¹⁸ recommend being in contact with participants not just when new data are needed, but also between such requests. Laurie³⁷ uses the term *keep-in-touch exercises* (KITES) to describe tactics for contacting participants between study requests to foster a sense of community and to keep contact information updated. Examples include updates about key findings, a change of address card or request, thank-you cards, and birthday or holiday cards. The communication approaches conveying the participant's value to the research project, and vice versa, are helpful for retention. Moreover, a study contact database will be more readily updated if participants are contacted relatively frequently rather than at long intervals (e.g., years).³⁷

Third, as with best practices for awareness and enrollment, study staff should use a mix of communication channels and tools to maintain contact with participants. **Tailoring and personalizing messages** to the target audience matters for retention. These messages should emphasize study benefits and exercise cultural sensitivity while addressing community priorities.^{35,38} Retention messages may need to include local culture and local people in order to adapt them to local communities. Abshire et al.³⁵ found that among studies that had strong retention rates, successful teams adapted their retention tactics on the ground by individualizing them to their participants in context-appropriate ways; examples included physicians and nurses leading group discussions for participants about disease management, encouraging participants to invite study team members to family gatherings (for a genetics study), and encouraging participants to submit artwork created by them or other family members. In short, working within the cultural context of a community and tailoring communication to individuals in creative ways can be beneficial for retention.

Mapping the Future with the All of Us Research Program

The AoURP is an innovative and ambitious research initiative intended to chart the future of biomedical science. By enrolling a million or more participants from diverse social, racial and ethnic, geographic, and economic backgrounds, as well as from all age groups and health statuses, the AoURP is creating what will be arguably the largest and most diverse data set available for health research. Such data could make precision medicine a reality.

The AoURP is challenging to implement, perhaps audaciously so. Making potential participants aware of the program, enrolling them, and retaining them over a long period of time require support from community leaders and clinical champions, as well as diverse engagement teams. In addition to possessing strong communication skills, cultural competence, and knowledge of the local communities, the engagement teams should have members with research, clinical, organizational, marketing, and even sales expertise. Some potential participants are likely to be wary of such a bold national program. Therefore, critical first steps for participant and stakeholder engagement are to explain the program's goals and potential benefits in ways that participants can understand and to nurture an environment of trust with communities, as well as across and within engagement teams. Such an environment will help the program conduct ethical, rigorous, and cutting-edge research that can grow and mature over time in partnership with participants.

Many important aspects of the AoURP are uncertain. For instance, what kind of information will the program be able to give back to participants, and when will it do so? What research questions will the AoURP data address? What impacts might the program have for families and communities? What role will the AoURP play in building a precise and personalized health care experience in the future? As RMC staff work to engage participants and stakeholders, they must know how to talk about these and other uncertainties. But there is one dimension about which

engagement staff can be certain. Just as the research facilitated by the AoURP has the potential to transform medicine, the engagement efforts to build trust in research, to foster new relationships with participants, and to share the potential promise of precision medicine with communities may yield equally transformative progress. In and of themselves, engagement staff investment in research, community wellness, and engagement are making a substantial contribution to improving our nation's health.

Appendix. Research Methods

Data Collection and Analysis

To develop best practices for engagement, we used the Rapid Assessment Procedure (RAP). RAP is a methodological approach for quickly synthesizing multiple data sources, refining and verifying emerging findings by iterating between data collection and analysis, and informing relevant stakeholders of findings in a timely manner. We synthesized the results of (1) a literature review on what a best practice is and on strategies and tactics for participant enrollment and retention in biobank and longitudinal surveys; (2) review of the engagement plans that RMCs submitted as part of their ISIAAs, the results of a Delphi consensus panel where RMCs identified key factors that may affect engagement, and the findings from a self-assessment tool of study engagement practices completed by RMCs; (3) semistructured interviews with RMC engagement leadership; and (4) site visits to three RMCs that had early engagement success.

1. *Literature Review on Best Practices and Engagement*

We conducted an integrative literature review to explain what a *best practice* is and to identify any best practices for participant enrollment and retention that might have been developed in similar types of studies.⁵⁶⁻⁵⁸ The integrative literature review is appropriate for synthesizing representative literature on an emerging topic. This approach allows us to draw on literature from different fields that uses a range of methods. This type of review is helpful for developing a preliminary conceptualization of the topic (i.e., how best to engage participants into a new type of research). By creatively combining insights from the management, social science, and health literatures, we developed an approach for determining what might be considered a best practice for participant and stakeholder engagement in the context of the AoURP and identified specific examples of best engagement practices from the three relevant fields.⁵⁶⁻⁵⁸

In collaboration with research librarians, we conducted a literature search of Business Source Complete (EBSCO), PubMed, and Web of Science electronic databases of academic peer-reviewed literature. *Best practice* is a common yet ill-defined term, so the first goal of the literature review was to define what we mean by *best practice* and to differentiate between *best practices*, *strategies*, and *tactics*. To address the first goal, we focused on the management literature. We searched Business Source Complete (EBSCO) and Web of Science databases using different variations of the search terms “best practice,” “promising practice,” “developing or designing best practices,” and “benchmarking.” The search period covered inception of the databases to October 24, 2017, when the database searches were conducted.

The second goal of the literature review was to identify best practices for participant recruitment and retention in studies that are similar to the AoURP, such as biobanking and

longitudinal or panel studies. Doing so provided insights into how engagement is described in the literature and identified best practices for participant recruitment and retention in similar types of projects. We also used results of the literature review to explore the potential effectiveness of engagement practices that the AoURP RMCs plan to use and to develop recommendations for improving RMC engagement strategies going forward.

To reach the second goal, we focused on the health literature and searched the Web of Science and PubMed databases using the terms related to longitudinal studies, biobanking, recruitment, and retention (see Text Box A.1).

Text Box A.1. Literature Review Search Strategy

- Search procedures for Web of Science: Topic search (ts)=(longitudinal OR biobank*) AND ts=(retention OR retain* OR recruit* OR nonresponse OR refusal* OR dropout* OR drop-out OR “dropping out”) AND ts=(participant* OR participat* OR member*)
- Categories searched with Web of Science: health care sciences services OR substance abuse OR psychology clinical OR health policy services OR medicine research experimental OR statistic probability OR social sciences interdisciplinary OR social sciences biomedical
- Search procedures for PubMed: retention[Title] OR retain*[Title] OR recruit*[Title] OR nonresponse[Title] OR refusal*[Title] OR dropout*[Title] OR drop-out[Title] OR “dropping out”[Title] AND longitudinal[Title] OR biobank[Title].

Our search terms identified 2,092 potentially relevant sources. We screened these sources using the following inclusion criteria:

1. peer-reviewed articles published in English in academic journals OR
2. trade articles published in English by reputable and credible organizations (in the case of best practices research only) AND
3. articles published in the last ten years (to help account for potential changes in communication technologies)
4. for PubMed: journals published in categories excluding dental journals (core clinical journals, MEDLINE, nursing journals).

After screening all articles using these criteria, we downloaded 1,418 sources into EndNote for further review. When reviewing the titles and abstracts of these articles, one researcher (SE) identified articles most relevant to the topic of our study using the following criteria:

1. defines “best practice” OR
2. explains strategies used to recruit participants for biobank or longitudinal survey studies
3. explains strategies used to retain participants in biobank or longitudinal survey studies.

At this stage of the screening, we excluded 473 articles that had unique populations of interest (e.g., drug users, children, teenagers) because they were often less relevant due to the unique ways researchers had to target, communicate with, and retain participants in those contexts. Nonetheless, we note that no articles were ruled out *a priori* based solely on their

population of interest or on other factors, such as country of origin (for example, several articles addressed recruitment and retention in Australian settings, and some of these were useful). We scanned the abstracts of the 945 remaining articles.

Our literature review was based primarily on close readings of approximately 290 sources containing information we deemed most relevant to our goals. To synthesize observations from the literature, SE reviewed the included articles and sorted them into three groups depending on the question each article helped to answer. The first group consisted of articles that included definitions of best practices. Many of these articles were trade publications with practitioner-targeted information that was not specific to health and health care. The second group consisted of articles that described participant recruitment in health-focused or longitudinal studies. The third group included articles that listed ways to retain participants in such projects.

We identified key themes from the literature by searching for examples of definitions of best practices and common recruitment and retention activities. While a handful of articles directly addressed recruitment and retention practices, in most of the sources, these practices were listed in the methods sections describing study design. This placement suggests a dearth of studies specifically focused on recruiting and retaining participants in longitudinal projects, highlighting the need to identify best practices for participant engagement in studies like the AoURP.

The literature review process was discussed and further refined during weekly team meetings, where we triangulated emerging findings from the literature review with the themes identified through the analysis of ISIAs, interviews, and site visits. In particular, we used the review results to finalize our approach to determining how to identify a best practice. We also discussed the degree to which what we were observing in interviews and site visits aligned with what we found in the literature; the extent to which the AoURP is unique, compared with the studies described in the literature we reviewed; and the degree to which the existing literature can help the AoURP going forward (e.g., with regard to recommendations related to retention).

2. Review of ISIAs and Affiliated Documentation

Each RMC completed an ISIA as part of its IRB submission for the AoURP. The ISIAs provided detailed plans for participant engagement and retention efforts across each site at each RMC. The RAND team requested copies of these reports with three aims in mind: (1) to review the proposed engagement activities, (2) to understand the team structures at each RMC, and (3) to understand the relationships between different sites within an RMC. We received and reviewed ISIAs from only four RMCs.

To get information on the ISIAs from the remaining RMCs and to supplement our review, we relied on materials provided by NIH at the onset of the project:

- All of Us Research Program Self-Assessment Tool Presentation (Cohn and Lee), presented at the 2017 Leadership Face-to-Face Meeting
- Spreadsheet of Engagement Strategies by Stakeholder; Spreadsheet of Compiled Outreach Methods, dated October 19, 2017

- Spreadsheet of Self-Assessment Tool Results, dated September 2017
- ISIA Analysis, v.2—Outreach and Engagement (Lee and Worthington).

In reviewing these documents, we identified target populations, staff recruitment and training plans, site interaction plans, specific tactics used by sites or RMCs for different phases of the participant recruitment process (awareness, engagement, enrollment, retention), engagement activities considered best practices by the RMCs themselves, and areas of concern as they rolled out their engagement work. We captured all of the information in a series of spreadsheets, modeled on the framework designed in the NIH reports, which we supplemented with information gathered through the interviews and site visits. The results of ISIA and document review informed the development of the interview guide and site visit protocols and provided preliminary structure to the code book for reviewing interview transcripts and site visit transcripts and field notes.

Together, the literature review and ISIA and document review informed definitions of best practices that were used throughout data coding and analysis. We defined best practices as those strategies meeting three criteria:

1. adopted by more than one RMC
2. perceived as effective or supported by the literature
3. potentially or actually measurable.

3. *Interviews with RMC Patient Engagement Leads*

We interviewed 15 participant engagement leads from nine of the ten participating RMCs. Representatives from one RMC did not respond to our invitations to schedule an interview. Interviews lasted one or two hours per RMC and were conducted via telephone.

The interviews followed a semistructured format to ensure comprehensive and consistent coverage of topics useful for identifying best practices for participant engagement. Interviews covered the following topics:

- **The engagement team:** These questions focused on team structure, composition, hiring criteria, and training.
- **Meaning of engagement:** This section of the interview protocol centered on how RMCs defined *engagement* within the AoURP and how that might differ from other projects they had staffed.
- **Engagement strategies:** Questions related to this topic explored how RMCs translated engagement into specific approaches to building participant awareness, enrolling them, and retaining them in the initiative moving forward.
- **Effective engagement strategies and tactics:** These questions asked which approaches were proving particularly effective for ensuring participant awareness and securing participant recruitment and retention, as well as which strategies and tactics had been abandoned or paused as less fruitful.

- **Meaning of engagement success:** This section of the interview explored questions on how RMCs and sites were defining *success* beyond reaching one million participants.
- **Ways to measure engagement:** This discussion addressed how RMCs and sites were tracking the success of different strategies and tactics.

Each interview was conducted by two qualitative researchers, with one researcher leading the interview and another one taking notes and asking clarification questions. The team-based approach to conducting interviews facilitated comprehensive coverage of topics in the interview, helped clarify topics that required further exploration in subsequent data collection, and streamlined the development of frameworks (e.g., the three Ms, domains of engagement) for organizing findings.

4. *Site Visits to Three RMCs*

Finally, a team of two or three researchers, which always included one of the co-PIs, conducted one or two daylong site visits to three RMCs located in different parts of the country. The RMCs were selected based on the length of time they had been enrolling participants and the range of participant engagement approaches they used as determined based on the ISIA review and telephone interview results. Within each selected RMC, we visited most sites (e.g., at least three medical centers) and a sample of engagement locations (e.g., waiting rooms, hallways, physical exam rooms, phlebotomy facilities), with an aim to observe the sites and locations of the highest-volume engagement.

During the site visits, we interviewed 11 RMC site leaders, 28 engagement staff, and eight other AoURP advocates. At one RMC, we also attended an RMC-wide meeting where we had a group discussion with 22 staff members. Most of these interviews were audio recorded and transcribed; verbatim notes were taken in a small number of instances when recording was not feasible or when interviewees preferred not to be recorded. The team also conducted walk-along interviews with the AoURP staff (e.g., recruitment coordinators) and support teams (e.g., mobile tour staff, champions). Both walk-along and sit-down interviews addressed topics similar to those covered during the semistructured telephone interviews described above but elicited additional details about specific sites. The teams toured the enrollment areas, observed staff meetings, and collected copies and photos of various program materials in situ. Importantly, team members did not observe actual patient enrollment efforts in order to protect the privacy of the public and participants.

The team doing each site visit prepared detailed notes, which included interview and observation notes. The latter focused on describing the facilities where engagement and enrollment activities take place, the use of AoURP-branded materials by RMCs, the interactions and group dynamics among RMC team members, the challenges and solutions devised to improve engagement, and anecdotes describing key engagement practices.

Immediately after conducting each interview, we summarized key engagement practices mentioned and added them to an interview abstraction spreadsheet. The abstraction process highlighted engagement activities mentioned in the interview (e.g., “hiring staff who are friendly”) along with a preliminary label of the type of practice, which phase of engagement it emphasized, and whether the interviewee considered it an effective practice. This abstraction data set was refined and revised as interviews progressed. This iterative processing of interview data through abstraction coupled with the results of the literature and ISIA reviews facilitated the development of a code book and the tracking of the reach across RMCs of various engagement practices.

All recorded interviews were professionally transcribed. Both transcripts and notes were coded using Dedoose, a cloud-based qualitative software analysis platform. While all RAND researchers participated in conducting the interviews and site visits, the two who did the coding (KS, SE) never participated in the same interview. When it came to coding, they split the work, with KS coding interviews and site visit notes led by SE or other researchers, and vice versa. The study PIs (DK and EB) reviewed the coding and discussed any disagreements with the coders until consensus was reached.

Although the initial code book was developed from a topic list generated through review of the abstraction database, results of ISIAs and document review, and the literature review, we refined and elaborated these topics based on themes heard across multiple interviews and evolving strategies for framing results (i.e., according to phase or target of engagement, emerging evidence on best versus promising practices, the three Ms framework). We also included several “other”-type codes to flag any emerging and unanticipated themes.

Once the data coding was completed, we finalized lists of best and promising practices by applying the three criteria for determining the best practices outlined above. The team finalized clustering of specific engagement strategies based on the facets of engagement (e.g., laying the foundation) that they addressed and then grouped concrete engagement tactics into engagement strategies. We then defined and identified markers, mechanisms, and metrics (the three Ms) of engagement and grouped them based on the facet of engagement that they were relevant to. In this manner, the team reached agreement not only on whether a strategy could be recommended as a best practice, but also on a framework for considering how engagement could be evaluated.

To protect participant confidentiality, we do not identify RMCs and sites that were included in our final sample. We also use codes (RMC A, RMC B, etc.) instead of RMC names throughout the report.

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