Research Ready

Guide for engaging clinical staff in research studies

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ALIGNING ACTION FOR HEALTH SM

Authors:
Rebekah Angove, PhD
Kytara Epps, MPH
Daniele Farrisi, MPH
Peggy Sanders, MSEd

As *more health research studies are taking place in traditional health care delivery environments, engagement of clinic staff in research activities has emerged as a key factor for success. However, clinic staff have not been the target of interventions for improved research implementation within health care settings. The Louisiana Public Health Institute (LPHI) conducted interviews with both clinic and research staff to learn more about their experiences and perceptions of clinic-based research. This guide describes interview findings and makes recommendations to research teams for successful engagement of clinic staff in future research studies.*

Introduction

Through administering the Research Action for Health Network (REACHnet), the Louisiana Public Health Institute (LPHI) has worked with outpatient clinics to implement pragmatic clinical research studies. Through those efforts, LPHI identified that lack of engagement of clinic staff and lack of knowledge of research fundamentals were key barriers to the successful implementation of studies that take place in outpatient clinical settings.

To address these issues, LPHI created the Clinic Staff as Unique Stakeholder Group in Patient-Centered Outcomes Research project (also known as Research Ready), which was funded by a Eugene Washington Engagement Award granted from the Patient-Centered Outcomes Research Institute (PCORI). The project had two main deliverables: 1) A staff training guide to increase their knowledge of basic research principles and procedures, and 2) A researcher guide to aid research staff in engaging clinic staff in research activities.

Both the training and guide were informed by qualitative research gathered through semi-structured key informant interviews with clinic and research staff. Twenty-eight total interviews were conducted. The interview participants were placed into two groups: Tier 1 – clinic staff and Tier 2 – research staff. The interview guides for each group differed to align with the role each have in implementing a research study, but both guides were based on a common set of guiding questions.

Key informant job roles by group
(in order of frequency)

Tier 1 - Clinic Staff	Tier 2 - Research Staff
Medical Assistant	Clinical Research Coordinator
Licensed Practical Nurse	Principal Investigator
Nurse Manager	Research Director
Registered Nurse	Research Assistant
Social Worker	Research Nurse
	Chief Nursing Officer

Introduction *(continued)*

The goal of this guide is to educate researchers on the perceptions and experience of clinic staff that assist with research and to encourage research teams to be proactive in bridging the gap between research and clinic staff in an effort to perform more effective studies.

In this guide you will find:

- **Key Recommendations**—Based on the interview results, these recommendations are organized into categories and designed to help you implement the results of our project.

- **Summary of Results**—In this section you will find a detailed summary of results, complete with quotes from our interviewees.

- **Additional Resources**—Resources include a link to the training workbook for clinic staff that LPHI also developed as part of the Research Ready project, as well as sample agendas to help you design more clinic-centric project planning and onboarding meetings.

Key Recommendations

Based on the findings of key informant interviews with clinical and research staff (detailed below), the LPHI team offers the following recommendations to improve the experience and success of implementing research studies in clinical settings. The recommendations are organized into categories that follow the typical sequence of research engagement: protocol development, site selection, onboarding, implementation, close-out, and dissemination.

Protocol development

- Aim to develop a research protocol that can be easily integrated into existing clinic workflows and systems. To accomplish this, speak with clinical staff (clinic manager, nurses, medical assistants, and/or front desk staff) to learn more about their current workflow and discuss feasibility of integrating study activities.
- Talking to medical providers about the proposed workflow and protocol, while helpful, is not sufficient. Support staff, such as medical assistants and nurses, have a better sense of the overall flow of the clinic.
- Speak to staff members representing each of the roles that will be executing research activities. A sample agenda for this study planning meeting is included in the Additional Resources section of this document.
- Simple tasks that are not time-consuming to perform work best for clinical environments (e.g. distributing surveys or collecting samples).
- Aim to maintain existing clinical workflows as much as possible and integrate study activities as seamlessly as possible.

Site selection process

- Learn about the patient populations of the clinics you're considering in order to ascertain whether they are a good match for your study.
- Ask the staff for their assessment of whether or not the study is appropriate for their population.
- To approach a clinic, start with the organizational leadership to get their support for using their site(s) to conduct pragmatic research. Then, ask to be introduced to the site manager who can share insight on the daily operations of the clinic and help coordinate meetings with clinic staff.
- Make sure organizational leadership buys into and understands pragmatic research and its benefits (resources) and drawbacks (potential lower patient volume). Engaged leaders will help promote staff buy-in for research activities.
- Clinic staff can help researchers understand common barriers that the patient population will have to research (e.g. health literacy, technology literacy, preferred language). Researchers should adjust their protocols to address these barriers.

Key Recommendations *(continued)*

- Select sites with a culture that is supportive or potentially supportive of research implementation such as those who have successfully participated in research before, whose mission is closely aligned with the aims of the study, or who serves the target population.
- Ensure that providers (MDs, NPs, PAs) are supportive of the study and of their role and the roles of their support staff in implementing it.
- Identify and address administrative barriers at each site that may impact the implementation of the study.

Onboarding

- The Additional Resources section of this report includes a link to Research Ready training materials for clinic staff. Clinic staff need a basic understanding of the research process and the value of research. Provide this training or work with clinic administration to ensure that it has been provided to all staff.
- Once the study has been approved, meet in-person with clinic staff to describe the study, review roles, and introduce study team. A sample agenda for this onboarding meeting is included in the Additional Resources section of this document.
- Use inclusive, accessible language in training and onboarding materials. Avoid scientific jargon as much as possible. Provide definitions for all scientific terms.
- Include all staff in onboarding whether or not they have a direct role in implementing the study because their work will likely be at least indirectly affected.
- For staff members who do have a role in implementing research, explain the role to them including how it fits into the bigger picture of the research project and who has authority over their work (e.g. CRC, clinic manager, etc.).
- Identify study team point of contact and share all relevant contact information including e-mail, office phone, cell phone, instant message, etc.
- Present the study overview at a lunch or breakfast meeting and bring food.
- Provide written materials and job aids that staff can refer back to during implementation.
- If you are unable to share certain information with the staff (due to blinding or proprietary restrictions), acknowledge that fact and explain why.
- Clinic staff want help communicating with patients about studies and answering patient questions. Provide talking points or FAQs and facilitate practice activities including how to handle and respect patient rejection of participating in the study.
- Work one on one with staff that will have a more specialized role in study implementation, such as medication administration or use of a new technology platform.
- Describe potential benefits and risks that study participants may incur. Remind clinic staff that patients will be informed of risks as part of the informed consent process.

- Plan for clinic staff turnover and/or rotation by providing onboarding materials and role descriptions. Meet with all new staff during their orientation period to provide study onboarding support.

During implementation/check-ins

- Ensure that point of contact or other study team member is available during clinic hours to answer questions and address issues.
- Learn the communication preferences of clinic staff (e.g. method, time of day) and honor these preferences as much as possible.
- Hold regular check-ins with clinic staff to share feedback on how they are doing (e.g. status reports), address their issues or concerns, maintain engagement, and reinforce understanding of the study purpose and protocol.
- Maintain a regular presence in the clinic to build rapport with staff.
- Visit clinic in person to observe and assist with study activities.
- Share site-specific progress on study metrics such as enrollment.
- Find ways to show appreciation for clinic staff that are assisting with study implementation. When possible, provide incentives to staff such as additional pay or paid time off.
- Help staff navigate and problem-solve when there are logistical challenges and the competing priority of standard patient care.
- Work with staff to anticipate challenges and ways to address them.
- Adjust workflows as needed while staying within the study protocol and minimizing disruption to other clinic processes.

End of study/ closing out

- Provide some type of closing communication either in-person, or via phone or e-mail.
- Recognize clinic staff for their role in the success of the study.
- Share any early metrics that may be available (e.g. number of patients enrolled, number of patients that completed the study, number of samples collected, number of surveys completed).
- Describe next steps and timeline of when results may be available.

Dissemination

- Share preliminary results of study with clinic staff as soon as possible.
- Share copies of related publications with clinic staff as they are published. Unless they are affiliated with an academic center, most clinic staff will not have access to scientific journals. Share the articles themselves, not just the citation or link to publisher's website.
- When sharing follow-up information, explain the impact of the study (e.g. how patient care may be affected, what additional research is planned).

Summary of Findings

The project team applied qualitative research methods to analyze the data collected in the key informant interviews and identified major themes related to the design and implementation of clinic-based research studies. The summary of findings below is grouped into six categories: relationship between researchers and clinic staff, communication, workflow integration, training and onboarding, site selection, and clinic staff relationship with patients.

Relationship between researchers and clinic staff

> " Get to know the staff... [It] helps the doctors and staff trust you and see that you want to help their patients. This makes them more receptive and willing to participate."
> — Tier 2 Informant

Building a relationship with clinic staff and being clear in communication is key for successful study implementation. Tier 2 informants, researchers with experience implementing studies in clinic settings advised research teams to build trusting, personal relationships with clinic staff members by being present in the clinic, being responsive to their requests, and learning their communication preferences. Having a respectful attitude and taking the initiative to learn about the clinic's culture and workflows can also build this trust.

Tier 2 informants also warned that clinic staff attitude can make or break a project. Getting buy-in from clinic staff is important because their attitude toward research (in general or toward a specific study) has significant impact on a study's success, specifically patient recruitment and fidelity to the protocol. Informants said that clinic staff tend to be more positive about a study if they understand it and if they have developed a good relationship with the research team.

Tier 1 informants felt it was important for research staff to maintain a regular presence in clinic. Research teams should aim to be as flexible as possible when integrating study activities into clinic workflows.

> " The [research] coordinator mainly talks to doctors. If we were included, it would be good."
> — Tier 1 informant

Both Tier 1 and Tier 2 informants recognized that incentivizing staff in some way can generate buy-in to participate in research. This can take the form of tangible compensation such as additional pay, or gestures such as thank you notes or staff meals. Some staff may also be incentivized to participate in research as a professional development activity.

Communication

Proactive and ongoing communication is also important. Tier 1 informants reported feeling that there was often a general lack of information that made participating and supporting studies challenging.

> **"** Give updates – how we are doing, what our recruitment numbers are, positive reinforcement to staff."
> *– Tier 1 informant*

Tier 1 and Tier 2 informants agreed that ongoing communication between the research team and clinic staff is key to ensuring all parties understand what needs to be done and how it needs to be done for successful study implementation. Regular communication with clinic staff is needed to keep them engaged in the study. Clinic staff are busy with their regular job duties and may forget about a study. The research team can help by providing reminders, ongoing support, and (when available) study results.

Pre-implementation communication is also important to ensure staff have adequate information about the study. Tier 1 informants said that they want to know the details of a study (methods, process, timeline, roles, etc.) early in the research project/process. They are interested in hearing the positive outcomes that can occur and they feel it is important to tell clinic staff ahead of time what is needed for a study.

After introducing the study, Tier 2 informants said that regular follow-up with clinic staff is needed to reinforce key messages and address questions or problems that arise. Tier 1 informants also expressed a desire for feedback from the research team regarding the progress of the study and the ultimate outcomes.

Tier 1 informants found it very helpful to have a point of contact from the research team who was available to answer questions and address issues that require immediate attention. Preferred methods of communication with this point of contact were phone call, e-mail, and instant messenger. Usually, the study coordinator or clinic support specialist fulfilled the role of point of contact; sometimes the role was fulfilled by a clinic staff champion.

Workflow integration

> **"** Why are we doing it? What's the benefit to patient? How am I going to incorporate this into my workflow when I already have 1,000 things to do?"
> *– Tier 1 informant*

According to the informants, clinic staff were involved with various research activities depending on the scope of their licensure/certification, the needs of the study, and the culture of the practice in which they worked. Clinic staff were commonly involved in recruitment of patients. Other activities included scheduling patients, giving injections, facilitating hand-offs to study coordinators, and sending or receiving status reports to/from the research team.

Tier 1 informants felt more motivated to participate in research activities that were simple, not time consuming, and/or had a high degree of in-clinic support from the research team. Both groups of informants overwhelmingly reported that short projects or activities were the easiest to imbed in a clinical setting. They either gave examples of these tasks (e.g. surveys, collecting samples) or cited "brief" as the reason a particular study design is optimal in a clinical setting.

Integration of study and clinical workflows was noted by both Tier 1 and Tier 2 informants as being a key factor in the success of clinic-based research studies. Unfortunately, both groups also cited it is a common challenge, and lack of integration was cited by Tier 1 informants as a reason for feeling less motivated to participate in research studies. Informants warned that it is difficult to integrate research activities into an already packed

clinical workflow. These time challenges can be further compounded by other barriers such as staff turn-over, staff rotation between sites, involvement of multiple clinical teams (e.g. specialist, primary care, pharmacy, and imaging), and juggling research priorities with clinical duties.

Informants' best practices for workflow integration include: matching established clinical workflows as much as possible; streamlining study activities with clinical activities to avoid duplication of work; working proactively with clinic staff to develop workflows and adjust as necessary. Tier 2 informants recognized that seamless (or near seamless) integration of study activities into a clinic setting requires time to plan and optimize. However, the group also noted that making this investment early in a study led to smoother implementation. Tier 1 informants echoed this

> **"** Keep in mind you are going into someone else's house. When you go to someone else's house you have to remember you can't tell them how they run their house."
> *— Tier 2 informant*

sentiment when they expressed the desire that researchers speak to them before implementing the study to co-develop study protocols that can be easily integrated into existing clinic workflows.

> **"** If I don't understand why we're doing research, I might blow them off."
> *— Tier 1 informant*

Tier 1 informants report that they want to be involved in the study planning process so they can inform the development of realistic protocols and workflows for their specific clinic settings. Clinic staff consider themselves to be the best people to share information and give feedback on clinical workflows. As such, they expect research teams to be proactive in seeking their advice on integrating study activities into daily clinic operations. This inclusion will ensure that the clinic and research teams are coordinated and staff are supportive.

Tier 1 informants expressed worry about being able to handle the unexpected challenges related to the study such as answering patient questions, responding to reports of side effects, or working with scheduling to ensure research activities (e.g. imaging) are completed — all while juggling the required tasks of the clinical encounter. Tier 2 informants reported positive experiences and successful strategies addressing some of these challenges. Examples include providing scripts and practicing patient recruitment, creating job aid documents, integrating the process into clinic workflow, and research team members being available to support clinic staff.

Training and onboarding

Both groups of informants agree that it is important to ensure that *all* clinic staff receive some sort of training about the studies that happen at their clinic. Lack of staff support was reported as a challenge to study implementation. Overall, having the entire department involved was reported as improving the research process and project.

Tier 1 informants noted the following content topics as helpful to their implementation of the research project: purpose, benefits, specific tasks they will be asked to perform, and tips on introducing the study to patients. Tier 2 informants advised that staff should also have, or be trained on, a general understanding of the research process, human subjects protection, and the value of research. Tier 2 informants said that a clinic's prior experience with research affects the type and amount of training required. Clinic staff that have implemented research studies in the past require less time to onboard to a new project.

Both groups cited in-person group training at the clinic site (ideally with breakfast or lunch provided) is an effective way to introduce a new study to clinic staff. Group trainings should be designed to be engaging to the audience and use accessible language, rather than scientific jargon. Tier 1 informants felt that learning from peers who have prior experience implementing studies in clinical settings can be helpful.

> " Some PIs think that research activities can start as soon as IRB gives approval, but that is not the case. They don't understand that other agreements and considerations must be addressed — legal, contracts, budget, finance, data agreements, pharmacy (to ensure meds are stocked), approvals from different departments."
> — Tier 1 informant

Tier 1 informants expressed the following needs in order to feel comfortable implementing research: an understanding of their role in the project, mastery of the skills to fill that role, training on special protocols and procedures, and an understanding of who has the authority to direct their work on the study. They reported that hands-on, one-on-one training was helpful in aiding them understand and feel prepared for their specific duties related to the research study because it gave them the opportunity to practice the tasks and, in some cases, experience the activities from the patient perspective.

Both groups of informants noted that a single training was not sufficient to ensure that staff understand all information related to a study. Written reference materials and follow-up visits to the clinic site were needed to reinforce the messages of the initial training and support study implementation.

The interview data revealed that many clinic staff lack basic research literacy. Tier 2 informants stated that clinic staff need to have a basic understating of research, both the process and the value it brings to clinical care and treatments, in order to understand the studies, explain them to patients, and be motivated to participate more fully. Tier 2 informants noted that research protocols often deviate from the processes and procedures that clinic staff have been taught in their professional training. Without understanding research principles, clinic staff can be very uncomfortable with the deviations from standard of care, unknown risks, additional standards, and limitations inherent in research. While CITI training is the accepted standard for training staff on human subjects research, most Tier 2 informants felt that it would not be effective or appropriate for training clinic staff. As part of the Research Ready project, LPHI has developed an introduction to clinic-based research training for clinic staff. A link to the training is provided in the Additional Resources section.

Site selection

The interview data indicate that the competing priorities of the research team (science), the clinic staff (patient care), and organizational leadership (financial viability) can cause barriers to implementing studies in clinical settings. Tier 1 informants reported several reasons their clinics would not participate in research. Most of these centered around lack of benefit to the department, clinic, or patients. Lack of time and resources was also mentioned. Tier 2 informants stated that administrative barriers such as contracting and the Institutional Review Board process can negatively impact the implementation of a clinic-based study. This is especially trying when multiple institutions are involved.

Tier 1 informants identified the following facilitators of study participation: access to new or different medications, increasing knowledge of care and/or treatments, benefit to the patients and/or organization, and being aligned with organizational expectations to participate in research. Tier 2 informants also recognized the role that organizational culture plays in study participation stating that organizational leadership's support (or lack of support) for clinic-based research can filter down to an organization's clinic staff, which can have a positive (or negative) effect on staff buy-in.

Some Tier 1 informants also spoke of the need for research studies to be appropriate and relevant to the patient population at their clinic. They saw this as another reason that reseachers should meet with clinic staff during the planning phase of the study.

Clinic staff relationship with patients

> " Keep in mind that the staff knows their patients. They care about patients and want you to care about them."
> — *Tier 2 informant*

Tier 2 informants recognized that clinic staff tend to have long-term, personal relationships with patients, especially those who have chronic conditions. This relationship results in clinic staff acting as gatekeepers of patient access, which can be both an asset and a liability for a study. Clinic staff may be willing to leverage their relationship with patients to assist with recruiting, but may be reluctant to do so if they perceive that the research poses risk to the patient.

Tier 1 informants want to understand how a research study may benefit or harm their patients. Clinic staff especially medical assistants, consider their primary role to be patient advocates and believe that they are seen by most patients as trustworthy. In order to maintain that trust, clinic staff want to communicate clearly and truthfully with patients about research studies, including addressing their questions and handling patients' doubts or rejections. Tier 1 informants suggested the use of scripts to help them communicate with patients about research studies.

The interview data reveal that a tension exists between clinical care versus research activities. Tier 1 informants were very clear that they prioritize regular patient care first, before research activities. Tier 2 informants agreed that clinical staff prioritize their perceived well-being of patients above the directives of a study protocol, which can lead to difficulties implementing a study with fidelity to the approved protocol.

Additional Resources

Sample Agenda for Study Planning Meeting

Recommended attendees:

- Research team: principal investigator, clinical research coordinator
- Clinic staff: administrators, medical director, site manager, providers, support staff representatives (medical assistants, nurses, etc.)

Recommended topics:

- Team introductions
  - Researchers
  - Clinical staff
- Overview of research study
  - Research question and objectives
  - Target population
  - Funder
  - Timeline
- Description of clinic
  - Services provided
  - Onsite capabilities (e.g. lab, imaging)
  - Description of patient population
  - Average volume (visits and/or unique patients)
- Alignment of research study with clinic mission and patient population
- Proposed role of clinic in research study (e.g. recruitment, sample collection, survey administration, etc.)
  - Description of resources and incentives that may be available to clinic and/or staff
- Discussion of implementation strategies – identify potential barriers and facilitators, develop preliminary workflow for clinic-based study activities
- Review action items and next steps

Additional Resources *(continued)*

Sample Agenda for Study Onboarding Meeting

Recommended attendees:

- Research team: principal investigator, clinical research coordinator, any other research staff that will directly interact with clinic staff
- Clinic staff: all clinic staff including: site manager, providers, nurses, medical assistants, phlebotomists, front desk, patient account representatives

Recommended topics:

- Team introductions
  - ▶ Researchers – identify key point of contact
  - ▶ Clinical staff
- Overview of research study
  - ▶ Research question and objectives
  - ▶ Target population
  - ▶ Inclusion/exclusion criteria
  - ▶ Risks and benefits to participants
- Research activities that will take place in clinic
  - ▶ Describe activities
  - ▶ Assign responsibilities
  - ▶ Review workflow
    - ▶ Make adjustments as protocol allows
  - ▶ Verify staff understanding

Research Ready training for clinical staff

As part of the Research Ready project, LPHI created a training workbook to introduce clinic staff to basic research principles and pragmatic research considerations. The electronic copy of the guide (in PDF file format) is available at the following link:
http://bit.ly/RRworkbook

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