

Health Literacy Case Study Highlights: Supporting participant retention in research

A Case Study from Washington University in St. Louis and the University of Florida, developed with the MRCT Center

BACKGROUND

It is important to include people who are vulnerable and medically underserved in research studies. This case study highlights a longitudinal, qualitative clinical research study that included:

- people who use prescription drugs other than as intended
- women who are commercial sex workers
- women who have been involved with the criminal justice system

Retention and follow-up were identified as areas that could be improved and might benefit the study population (and the researchers) in the long run.

APPROACH

Health literacy is recognized as being two-sided, involving both the research participant and the study team. As such, it is important for the study team to understand the study population and address possible challenges to study participation.

Throughout this study, the team worked with the study population to keep them engaged and connected, ultimately leading to better retention and follow up. They did this by:

- 1 Sharing detailed information with participants about study expectations and the importance of follow-up by using Study Commitment Contracts.
- 2 Collecting thorough contact information from participants for follow-up purposes by using Locator Forms.
- 3 Practicing extensive outreach to the study population. This included actively and frequently engaging with participants in order to understand why study participation was challenging.

Clear research communications should highlight:

- Why the study matters
- What is expected of participants
- Why the participant's data is so important
- How the study team will involve and reach participants





STUDY COMMITMENT CONTRACTS

A Study Commitment Contract is a summary of the key points of participation and the expectations of being in the study. It is a contract between the participant and the researcher and considered similar to a promise.

- These contracts were used to help participants understand why their participation was so valuable and appreciated. This was especially important when participants experienced housing insecurity or other challenges that impact someone's ability to stay in a study.
- The research was always described as voluntary while also helping the potential participant understand the expectations of the study and feel empowered by their participation.

Commitment Contracts highlight the value of study participation



SAMPLE: COMMITMENT CONTRACT

I understand that I have been selected to participate in the ABCD study. By signing the Informed Consent, I am saying that I understand the commitment I am being asked to make.

I promise that:

1. I will make every effort to keep my appointments because I understand that the staff has reserved time just for me.
2. I will be on time for our appointments. If I have to cancel an appointment, I will call at least 24 hours in advance.
3. I will be honest during the interview and I am willing to be truthful in all my responses in order to help the research project.
4. I understand that the study staff will share any research findings with me
5. I understand that the study staff will always have my best interest in mind.

Signature

Witness

Date



LOCATOR FORMS

A Locator Form is a tool to collect pertinent contact information that would allow a participant to be reached more easily.



SAMPLE: Locator Form + Script

We'd like the names of some relatives or friends who would always know how to reach you. If your parents are still alive, could I have their name, address, and telephone number?

Name:
Relationship: Mom/Dad
Address:
City:
State:
Zip:
Phone:

A. Could I have this information for another close friend or relative?

Name:
Relationship:
Address:
City:
State:
Zip:
Phone:

B. Could I have the name of another relative or friend who would always know how to reach you?

Name:
Relationship:
Address:
City:
State:
Zip:
Phone:

C. Is there another friend or relative who would always know how to reach you?

Name:
Relationship:
Address:
City:
State:
Zip:
Phone:

EXTENSIVE OUTREACH AND PARTICIPANT ENGAGEMENT



The team was trained to increase phone calls and home visits to ensure the most complete dataset could be captured.

The study team member called and offered flexible times to meet with the participant in an effort to:

- > understand how continued study participation could be supported
- > review why continued participation was of vital importance to the study
- > try to retain the participant in the study

WHO WAS INVOLVED?



The Principal Investigator

Developed and put into practice the intensive enrollment and follow-up process.

Study team

Team members were committed to following up with study participants.

IRB

The IRB approved the enrollment and follow-up plan after understanding the importance of intensive follow-up with the study population.



“Lost to follow-up” included “soft” no’s such as unreturned calls and no-shows. The study team tried to reach the participant to communicate the team’s objectives and understand what happened.

Did the study team do something to upset them?

Did something happen in their life that changed their feeling about participating (e.g. a relapse)?

Did they move or change phone numbers? Were they aware the study team was looking for them?

Did life get busy and the study wasn’t a priority – meaning the study team had to consider making the study logistically easier?

If a person confirmed they no longer wanted to be in the study (which rarely happened), this was documented as a final withdrawal and no future contact was made.

OUTCOMES

SUCCESSSES

One study of 479 participants was able to **increase its follow-up rate from the mid-80s to 96.6%!**

- > Retention efforts reportedly made participants feel they were valued and important.
- > Their contributions were acknowledged, their time appreciated, and their data essential to answering the larger question being posed.

By reaching out to participants, the study team could confirm whether they no longer wanted to be part of the study, needed extra support to continue, or were a verified loss to follow-up.

CHALLENGES

Since this research team worked with hard-to-reach populations, the team collected more contact information than usual in order to ensure successful follow-up. Gathering all the information took additional time and staff resources.

Lessons Learned:

- Detailed contact information was key to ongoing communication with participants. This was important for safety and well-being, as well as for collecting necessary data.
- Explaining the need for more intensive outreach and follow-up to the IRB allowed for novel retention efforts to be used.
- Follow-up often required up to 6 'touches' in order to get the required data. Not answering the phone or missing a visit was often not an intentional 'no' to ongoing study participation.
- Social connection was an important part of research participation and a person's willingness to continue in a study.
- Discussing difficulties at study team meetings was helpful. Sometimes, recruitment and retention were improved by changing what study team members said or communicated.



The study's follow-up rate was increased to 96.6%!



RECOMMENDATIONS

The activities in this case study embodied health literacy best practices of engaging the study population to demonstrate that their participation is valued and communicating the importance of ongoing participation.

To improve retention and better understand the communities you work with, consider integrating the following into your research processes:

Time to explain to participants why both initial and follow-up data is so valuable to the outcomes of the study.



Commitment Contracts can help facilitate that conversation and emphasize importance.

In depth collection of contact information to help find participants and support follow-up.



Detailed locator forms communicate the importance of continued follow-up.

Dedicated time for and training of study team members to perform outreach and participant tracking.



Requests to visit with the participant to discuss the study were not only accepted by participants but appreciated.