Supporting participant research retention using community engagement and health literacy best practices

A Case Study from Washington University and the University of Florida, developed with the MRCT Center
In this case, the researcher conducts longitudinal, qualitative clinical research studies specifically with vulnerable, hard to reach, and medically under-served populations, such as:

- 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

These individuals are important to include in research.

Retention and follow-up were identified as areas that could be improved and could benefit the study population (and the researchers) in the long run.
How this is an example of health literacy in clinical research

- Health literacy is two-sided - it involves both the research participant, and the study team
  - It is important for the study team to understand the proposed study population and address possible challenges to study adherence.
  - Health literate 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

- This case demonstrates how the study team worked with the study population to keep them engaged and connected, ultimately leading to better retention and follow up.
How the research team started working:

The study team:

1. Shared detailed information with participants about study expectations and the importance of follow-up (via study “commitment contracts”)

2. Completed “locator” forms with participants for follow-up purposes

3. Practiced extensive outreach to the study population
   • Actively engaged participants who were difficult to reach in order to better understand the reasons why study participation may be challenging
A study commitment contract is a summary of the salient points of participation and the expectations of being in the study. Using such contracts was one way the study team helped participants understand why their data are so valuable and ongoing participation so appreciated:

- This was especially important in this research because many participants experience housing insecurity and other challenges that can affect their ability to stay in a study.

The research is always described as voluntary.

- At the same time, study “commitment contracts” ensure that the potential participant understands the expectations of the study and takes ownership of their ongoing participation.

Commitment contracts highlight the value of study participation.
Commitment Contract Example

I understand that in order to help the research project, I must be honest during my interview. I am willing to be truthful in all of my responses.

1. I won’t be disruptive at this site or while involved with the groups, if I am assigned to group.
2. I will not reveal the names of any woman I see at the site or in group, to protect all of our privacy.
3. I will make every effort to provide my own transportation to the interviews and groups.
4. I will be on time for my appointments. If I have to cancel an appointment, I will call at least 24 hours in advance.
5. If selected for group, I will attend the sessions.
6. I understand that in order to help the research project, I must be honest during my interview. I am willing to be truthful in all of my responses.

________________________
Signature

________________________
Witness

________________________
Date
2. Locator Forms

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

In this study, the research team collected at least three contacts in order to increase the likelihood that a study participant could be followed effectively and be found if necessary.

A script was developed using health literacy best practices to explain the purpose of the form so that locator data were collected thoroughly and correctly.
### Locator Form Example

<table>
<thead>
<tr>
<th>Question</th>
<th>Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td></td>
</tr>
<tr>
<td>Could I have the name of another relative or friend who would always know how to reach you?</td>
<td></td>
</tr>
<tr>
<td>Is there another relative or friend who would always know how to reach you?</td>
<td></td>
</tr>
</tbody>
</table>
3. 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
A note about the outreach process

• The study team considered “lost to follow-up” to include the “soft” no’s – a person who didn’t return calls, show up for appointments, etc.

• The goal was to reach the person to communicate the study team’s objectives and make sure the study team understood had happened to the participant.
  • Did the study team do something to upset them (violate their expectations)?
  • Did something happen in their life that changed their feeling about participating (e.g. a relapse)?
  • Did they move or change telephone numbers, so they weren’t even aware the study team was looking for them?
  • Or was it that life got busy and the study wasn’t a priority – necessitating that the study team consider making the study logistically easier?

• In all cases, a person confirmed desire to no longer be in the study (which rarely happened) was documented as a complete and final disposition and no future contact was attempted
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 searching for remaining and hard-to-find study participants

• IRB
  • The IRB approved the enrollment and follow-up plan after being provided with sufficient information to understand the importance of intensive follow-up with the study population.
Successes

• One study 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 determine whether they no longer wanted to be part of the study, needed extra support to continue, or were a verified loss to follow-up.

*https://www.ncbi.nlm.nih.gov/pubmed/8842633
Challenges

• Since this research team works with hard to reach populations that sometimes struggle with housing stability, the team collected more contact information than usual in order to ensure successful follow-up with the participants.
  • The research team created a detailed “locator” form that included all the contact information needed from participants
  • That said, gathering all the information took time and staff resources.

Pro tip:
The study team also kept checking in with the participants and maintained current contact information throughout the study.
Lessons Learned

1. **Collection of detailed contact information** if often a critical piece of being able to continue communications with participants.
   - This is important for safety and well-being, as well as for collecting necessary research data

2. **Working with the IRB** to ensure understanding of the need for more intensive outreach and follow-up allowed for more novel retention efforts to be implemented

3. These activities embody health literacy best practices to engage the study population in order to demonstrate that their participation is valued and ensure the importance of ongoing participation is communicated.
Lessons Learned

• Follow-up often requires 6 ‘touches’ in order to get the required data.
  • Not answering the phone or missing a visit may not be an intentional ‘no’ to ongoing study participation
  • If a participant declines upon confirmatory follow-up contact with a study representative, they are then removed from the study

• Social connection is such an important part of research participation and a person’s willingness to continue in a study.

• Discussing difficulties at study team meetings is helpful.
  • Sometimes, recruitment and retention can be improved by changing what study team members say or communicate.
Recommendations

- **Integrate 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 may 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 but appreciated.
  - A detailed explanation of the follow-up processes to help the IRB in their review and approval
<Insert links to one or two of Cottler’s relevant papers>

MRCT Center website Cultural consideration at recruitment: https://mrctcenter.org/health-literacy/trial-life-cycle/overview/recruitment/#1548959645790-6cb0de9e-b695

MRCT Center website Engagement techniques to consider once participants are enrolled: https://mrctcenter.org/health-literacy/trial-life-cycle/overview/on-study/