Participant Recruitment and Retention in Clinical Research

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Participant Retention: The goal is 100%

- Low follow up rates threaten study validity & final analysis
  - Internal validity (Population differences)
  - External validity (Generalizability)

- Aim: reduce study attrition by having a follow-up strategy in place before the first participant is enrolled
Rapport Building with Site and with Study Staff

Rapport at every level
- Consider rapport contagious
- Organizational level
  - Scheduling and space allotment
  - Identify the person who knows what is going on at the site
- Which staff will you be working with?
  - Who will help you connect with potential participants
  - Whose workspace will you be sharing
  - Whose equipment will you be using
  - Whose services will you be using
- PI and Director level: friendly and collaborative
Diagnose and Address Barriers Collaboratively

- Regular communication
  - Site staff
  - Research team
  - Team meetings and calls to brainstorm potential barriers and solution

- Clear documentation of participant interactions
  - Helps identify pattern, problems
  - Enables prediction of behaviors
  - Target for appropriate strategy
Preparing to Recruit: MOP & SOPs

- Tracking forms
  - Locator forms
  - Recruitment ledgers
  - Database/spreadsheet
- Procedure walk through AND role play:
  - Time every activity, including travel
  - Equipment needs and availability
  - Categorize location needs in terms of patient privacy, equipment security
- Site-specific recruitment modifications
  - Recognition that environments are unique
  - Where in each site will recruitment take place
  - How will study staff gain access to clients
  - IRB variations in requirements
  - Staffing allocation
Preparing to Recruit

Roles and Responsibilities

• Who is doing what?
• Cross Train: who backs up whom?
• Reduce burn-out
  • Mix up tasks, responsibilities, caseloads
  • Keep everyone up to speed on study activities
  • Keep up variety
  • Seek interviewer input
  • Weekly brainstorm sessions
Tracking Recruitment & Retention

• What do you need to track?
  • What tools and training is available?
  • What frequency: daily, weekly, DSMB meetings

• To whom do you need to report?

• How can sites benefit from tracking?
  • Participant windows
  • Activity deadlines
  • Lists of incomplete activities
  • Upcoming appointments
  • Reduce redundant work or data entry in multiple locations
Automated Reports

• Recruitment
  • Total recruited
• Screened/enrolled but NOT recruited
• Retention
  • Reminder contact dates
  • Missed reminder contacts
• Follow-up Windows
  • Upcoming appointments
  • Missed appointments
Retention Tracking

• Monthly contacts
  • Reminder letters
  • Reminder calls/emails/texts/social media
• Participant locator confirmation at baseline
• Recruitment Coordinator
  • Track to individual level to keep teams on target
  • Liaison between teams to share ideas and strategies
  • Offer retention quality assurance
Follow Up Strategy

- **Contact Efforts**
  - Phone reminders
  - Mailed reminders
  - Home/field visits
  - Text messages
  - Emails
  - Outreach
  - Participant on-site visit
  - Participant phone calls

- **Tracking Documentation**
  - All contacts
  - Frequency
  - Duration
  - Type
  - Content
Follow Up Strategy: Phone Call

• Keep in regular contact between appointments
  • Update/add to contact information
  • Remind participant of follow-up date
  • Offer new appointment card
• 2 weeks and 48 hours before scheduled appointment
  • Confirm contact information
  • Remind participant of appointment
  • Confirm transportation needs
• Call protocol
  • Call primary and secondary contact numbers
  • Leave no more than one message daily
  • Follow participant preferences in leaving messages, identifying project or study staff
Follow Up Strategy: Failed Scheduled Contacts

- Use all locator information
  - Phone all contacts
  - Home visits
  - Local hangouts
  - Search additional databases: county, state, national offender, court records searches
  - Additional reminder mailings
  - Email
  - Text messaging
  - Social networking sites
Follow Up Strategy: Reminder Letters

- Monthly mailing between appointments
- Additional strategies:
  - Certify letters
  - Request return receipt
  - Stamp “Forwarding address correction requested”
  - Include address correction/confirmation forms
Follow Up Strategy: Missed Appointments

Within 2 days of a missed appointment:

• Phone all contacts in locator form
• Conduct home visit
• Search local hangouts
• Search additional databases
Follow Up Strategy:
Home Visit

- Cover daylight hours, after 5pm, weekends
- Two staff members
- Cards with contact number and appointment date
- Confirm participant address with neighbors if possible without violating privacy
Response Strategies

• The harder they are to reach, the more touch points are needed

• Where are their drift-back points?
  • Living with family or friends
  • Living in shelters or on the street
  • Incarceration or treatment facilities
    • Restricted areas
    • Assigned case workers or parole officers
Assure Study Follow-Up

• Your study is not your participant’s priority; it’s yours
• Know your individual participants
  • Who needs extra attention
  • Build case files with clear, individualized notes
• Keep constant communication and maintain the relationship
  • With participants: they need to know you are thinking of them
  • With their contacts: they need to trust you. They need to like you. They need to be your allies
Protocol Adherence Drift

- **Prevention**
  - Reports help stay on top of things
  - QA monitors identify developing problems
  - Staff meetings address procedures, challenges, and maintain unity of understanding
  - Procedure observations: walk-through, session recordings help identify issues

- **Refinement**
  - MOP and SOPs are fluid, actively refined tools
  - Clarify and address ongoing modifications and surprises
  - Re-training as needed for all staff