

Principles of Recruitment: Human Subject Recruitment Strategies, Tactics & Resources

“No one is as interested or enthusiastic about your study as you are.”



From the Patient Perspective

Clinical Trial Participation
is a function of

Awareness



Education

+

Credibility



Responsiveness
– Relationship



Communication

Peril (risk)



Inconvenience

(c) 2008

cpp inc

Strategies

There are 3 keys strategies to keep in mind when developing a recruitment and retention plan:

1. Feasibility Assessments
2. Establish and manage relationships
 - i. Know your recruitment sites/partners
 - ii. Know your subjects
3. Multiple approaches

Feasibility Assessment

- Poor enrollment is due to poor recruitment plans, but also other factors such as poor study design
 - Keep the study as simple as possible
 - Remind participants of the “big why”

Feasibility Assessment

- Think about feasibility from the site perspective.
 - How many potentially eligible patients?
 - How many would be interested in study?
 - What is the staff's experience with research participation?
 - What is the participant's perception about study risk?
 - How much can the study team realistically support recruitment efforts?
 - Administrative burden
 - What are the staff's training needs?
 - What is the level of understanding of research participation across the study team

Feasibility Assessment

- Use your past recruitment and retention experience to create a plan.
 - What has worked (and not worked) in the past?
 - What rates are realistic?
 - Track and use your data
 - Use evidence from the literature
 - Identify new opportunities to identify participants
 - Future research registries
 - EMR
 - Social media

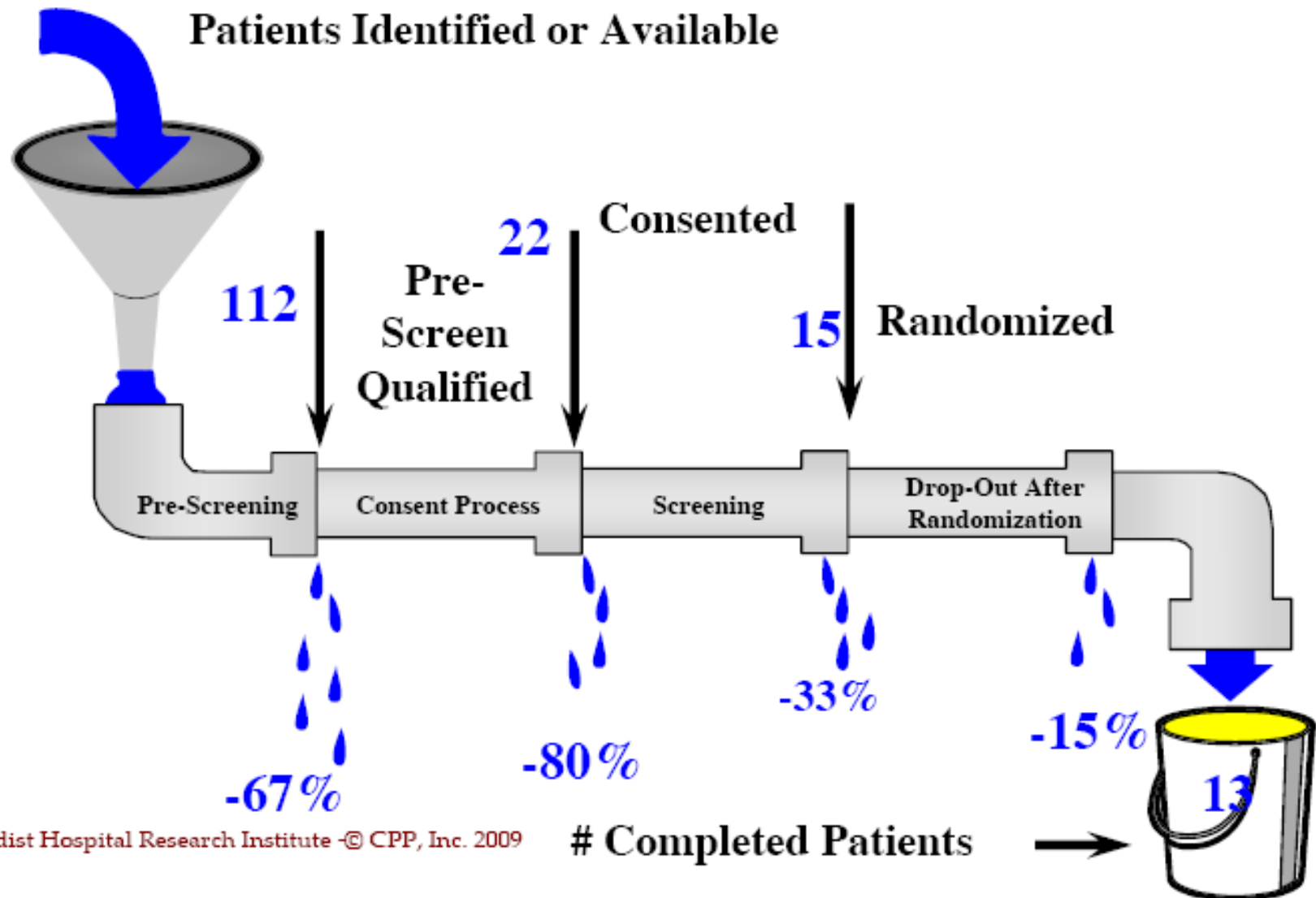
Examples of Feasibility Assessments

Systematically Estimating Enrollment:

The "Leaky Pipe" Analysis

236

Patients Identified or Available

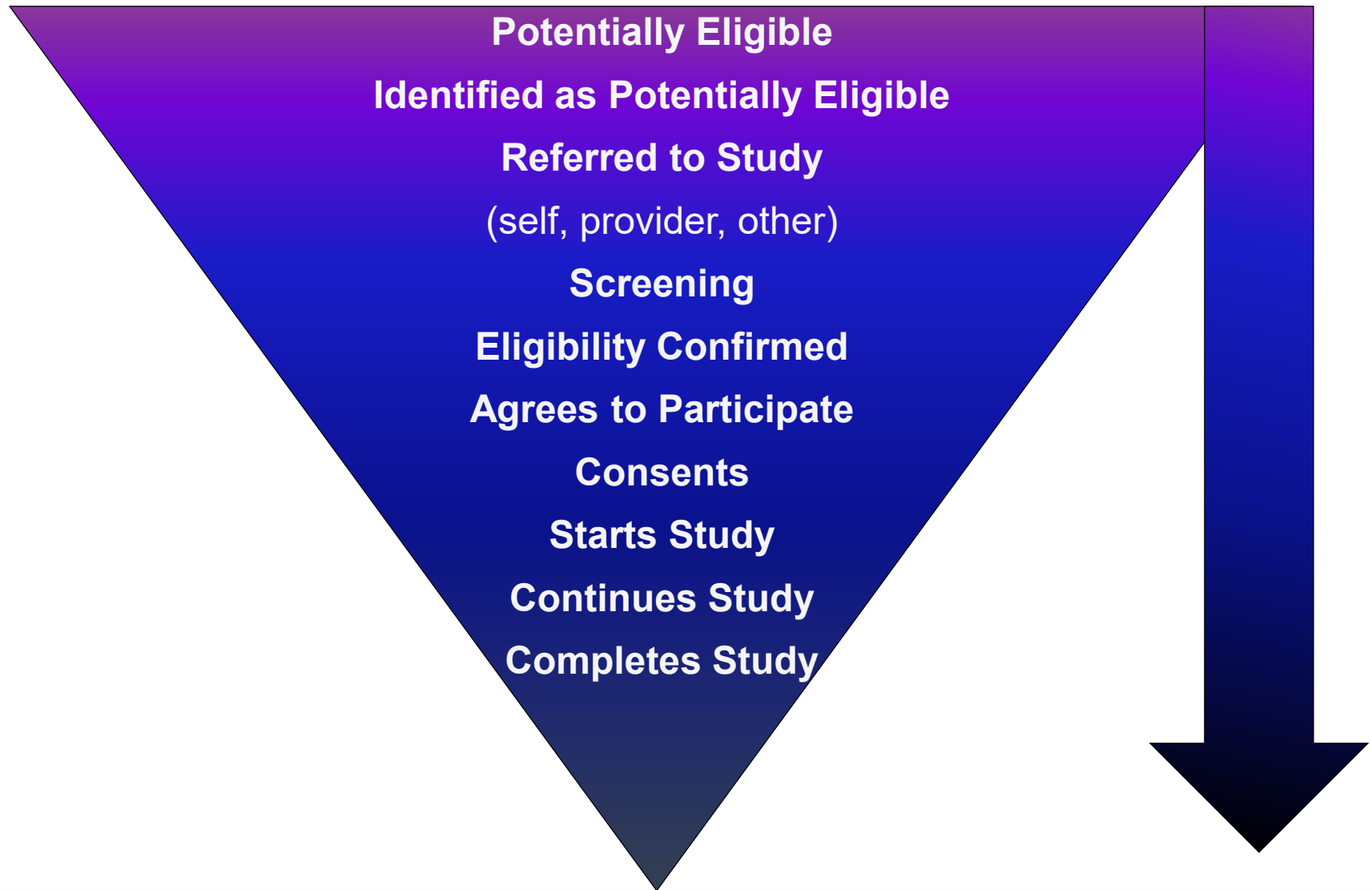


"Top Down" Funnel Calculations		
Funnel Parameters and Stages	Values	
Enrollment Period (months)	9	
# of Sites	20	
# Patients at a Given Site with Diagnosis or # Patients Available Across All Sites	200	
% Lost During Pre-Screening	0.33	
% Decline to Participate	0.8	
% Lost During Screening	0.65	
% Drop-out Post Randomization	0.25	
Funnel Calculations	Projected Values	
Patients Available	200	
Pre-Screen Qualified	134	
Consented (Enrolled)	27	
Randomized	9	
Completed	7	
# Enrolled / Month	3	
Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	10.0	1.1
# That Will Need to Be Consented	1.3	0.1
# That Will Need to Be Randomized	0.5	0.1

Reverse or "Bottom Up" Funnel Calculations

Funnel Parameters & Stages	Values	
Enrollment Period (months)	9	
# of Sites	20	
# Patients That Will Need to Be Identified	768	
% Lost During Pre-Screening	0.33	
% Decline to Participate	0.8	
% Lost During Screening	0.65	
% Drop-out Post Randomization	0.25	
Funnel Calculations	Projected Values	
Patients That Need to Be Identified	768	
Pre-Screen Qualified	514	
Consented (Enrolled)	103	
Randomized	36	
Completed	27	
# Enrolled / Month	11	
Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	38.4	4.3
# That Will Need to Be Consented	5.1	0.6
# That Will Need to Be Randomized	1.8	0.2

Recruitment Funnel



Example Feasibility

- Title: Comparison of low dose and high dose folic acid in women trying to conceive or early in pregnancy (months)
- Target Enrollment = 200 women age 18-45 years
- Statistical data:
- Monroe County population=749,606
 - 51.7% is female
 - 16% is black or African-American
 - 7% of population is ages 18-45
 - Fertility rate: 63.0 births per 1000 women aged 15-44 years per year
- 30% of participants fail pre-screening.
- 20% will consent and enroll.
- 10% of subjects enrolled will drop out.

Recruitment Funnel

Potentially Eligible = 744,344

Female = $749,606 * 51.7\% = 387,546$

Aged 18-65 = $387,546 * 39.4\% = 152,693$

Number of pregnant women = $245,704 / 11.1 = 13,756$

Screening = $22135 * 70\% = 9,629$

Consents = $15494 * 20\% = 1,926$

Completes Study = $3098 * .90 = 1,733$

Would need to reach 11.5 %
of target population to
get 200 participants.

Recruitment rate-
How many participants
per week or month do you
need?

<http://www.towncharts.com/New-York/Demographics/Monroe-County-NY-Demographics-data.html>

https://www.health.ny.gov/statistics/chac/birth/b42_26.htm

<https://www.census.gov/quickfacts/table/PST045216/36055,36>

Recruitment Data

Set up data collection such that you can answer

- where in the pipeline/funnel you are or are not having success – where is the fall off
- if you are recruiting from different sites what is the pattern from different sites
- if multiple enrollers are involved what is the pattern across enrollers
- if recruitment happens different days of the week or in different time periods (e.g. days, evenings) what is the pattern across these different periods
- if you need certain underserved populations, what is the pattern of their recruitment and retention

Data Use

- Recruitment and retention not viewed as a science
 - Not viewed as a problem to be solved with data
- Recruitment data are monitored but not analyzed
 - No data, missing data or data collected not useful, usable
 - Lack of data is a missed opportunity to help inform future studies
- Figure out where people heard about the study
 - Track success from each source
- *Systematic* plan
- *Systematic* evaluation
- Resource
 - Tracking Log

No data?

- Learn what has worked for others
- Talk with those in your field
- Conduct lit search
 - [http://www.ncbi.nlm.nih.gov/pubmed/?term=%28patient+selection+OR+research+subjects%29+AND+%28randomized+control+trial+as+topic+OR+clinical+trial+as+topic+OR+biomedical+research+OR+multicenter+studies+as+topic+OR+retrospective+studies+OR+prospective+studies+OR+case-control+studies+OR+cohort+studies+OR+human+experimentation+OR+health+surveys+OR+questionnaires%29+AND+recruit*+\[ti\]](http://www.ncbi.nlm.nih.gov/pubmed/?term=%28patient+selection+OR+research+subjects%29+AND+%28randomized+control+trial+as+topic+OR+clinical+trial+as+topic+OR+biomedical+research+OR+multicenter+studies+as+topic+OR+retrospective+studies+OR+prospective+studies+OR+case-control+studies+OR+cohort+studies+OR+human+experimentation+OR+health+surveys+OR+questionnaires%29+AND+recruit*+[ti])
- Test your ideas
 - Conduct focus groups with potential participants
 - Conduct surveys

Relationship Management

Know your recruitment sites/partners

- What are their barriers/facilitators
- Is everyone on board?
- Be visible/follow-up
 - Appreciate them

Relationship Management

Know your (potential) subjects

- Do they even know about the study?
- What are their participation barriers/facilitators
 - Logistic, attitudinal
 - Do they understand the study requirements?
- Appreciate them

Multiple approaches

- Have a PLAN!
- Best and worst case enrollment scenarios?
 - Expect attrition
- One method is not enough
 - ResearchMatch.org
 - Track success from each source

Marketing and Advertising

- RECRUITMENT as a form of HEALTH COMMUNICATION
 - Establish trust
 - Convey a meaningful and informative message
 - Empowering people in their search for treatment or ways to improve their health
 - Understanding your audience
 - Understanding the health challenges they face
 - Building an identity (branding)
 - Providing information that is easily accessible and understood.

Marketing and Advertising

- Use the four Ps
 - Product, price, place, promotion
- Product
 - Participation
 - What are the benefits of participating
- Price
 - Always a price
 - Minimize what the subject believes he or she must pay
- Place
 - Locate the recruitment, enrollment and study participation at sites that reach your audience
- Promote
 - The recruitment and study using creativity and through channels and tactics that maximize contact with and interest among the target population

Marketing and Advertising

- Newspaper
- Radio
- Television
- Bulletin Boards
- Posters
- Flyers
- Patient Information Letters
- Websites
- Social Media
- Health Fairs
- Craigslist
- Pocket cards for physicians

Do not rely on only one method!!

Marketing Budget

- Recruitment costs are almost never budgeted
- Plan ahead and include in grant
- Size the recruitment effort for the size of the budget
- Timing is everything, time ads with events

Duke Center for Living-STRRIDE 1

Advertising Method	Percent screened/enrolled	Screening Time per person (minutes)	Ad cost per person (\$)
Local Newspaper	8%	148	48
Special Event Ad	26%	47	35
Flyer	16%	75	18
University newspaper	13%	92	0
Radio	7%	180	190
TV	3%	353	205
Personal Referrals	17%	70	0
Other	2%	688	333
Total	10%	120	40

Recruitment Materials and Subject Payment

- Compensation is an important for successful recruitment:
 - Investigators must adequately describe all recruitment methods and plans for subject payment
 - Recruitment materials and payment methods must meet the standards outlined within your institution's IRB guidelines.
 - Investigators must submit to the IRB any revisions to recruitment material or plan prior to implementation

Recruitment Materials and Subject Payment

- Include in your IRB application
 - Ad info
 - Mode of communication
 - Final copies of printed materials
 - Final audio or video scripts
- Ensure that materials do not:
 - Imply a favorable outcome
 - Use exculpatory language
 - Emphasize payment
 - Do not promise free payment
 - Do not use terms new treatment, medication or drug
 - Do not make claims not in line with FDA labeling

Ad Design-Have “The Right Stuff”

- Why do it?
- Who should do it?
- How do you do it?

Have You Used Propecia for Hair Loss?

If you are a male between the ages of 18 and 50 and
have used Propecia for male baldness,
you could be eligible for a clinical research study.

Researchers at Baylor College of Medicine
are looking at possible Propecia-related side effects.

Participation in the study will require one visit.

To see if you qualify, please email
Sharon Harrison at sharons@bcm.edu
or call (713) 798-2240.

Living with MS?

Other people like you who are being treated for their MS with a disease-modifying therapy have volunteered to join a program to better understand the long-term safety of these treatments.

You may qualify to participate in this voluntary research study if you:

- Are between the ages of 18 and 65
- Have been diagnosed with relapsing MS
- Have recently started taking a disease-modifying therapy

Talk to your doctor to learn how you can participate or for more information call:

601-420-5810

Precise Research Centers
Flowood, MS



PASSAGE[™]



Registries

- Websites where participants can register if they are interested in research
 - UR Health Research website
- Resources
 - Local Registry
 - <http://www.urmc.rochester.edu/health-research/>
 - Flag created in medical record and can be included in i2b2 report
 - Research Match
 - <https://www.urmc.rochester.edu/research-subject-recruitment/recruitment-tools/research-match.aspx>

Social Media

Guidelines for Research Using Social Media

- Social media communications (ads, online-diaries/surveys, text messages, info about study progress must be reviewed by the RSRB)
- Make sure you are using a URMC Marketing approved tool or site
- Avoid use social media to collect PHI
- Measures should be taken to ensure privacy

Social Media-Pros

- Convenient
- Subjects often want to discuss their experiences
- May encourage enrollment and retention
- Makes subjects feel like they are part of a community and their contributions are recognized
- Good for recruiting populations that are difficult to reach
- Broader access

Social Media-cons

- Information can be forwarded on to people who are not targeting
- People may be willing to say things anonymously they would not say in person
- Examples of things that could confound a study if on-study participants share info on-line:
 - Attempts to unblind treatment assignments
 - Encouraging use of off-study lab testing
 - Encouraging non-adherence to study regimen
 - Falsifying eligibility status
 - Misinformation on adverse event profiles
 - Providing medical advice, discouraging reporting to investigators

What to do?

- Ask subjects not to participate in public discussions during the study
- Add language addressing this into your informed consent

Companies that will help with social media

- YuziLabs/ studypages.com
 - Building platform that can handle multiple sites and also has a dashboard that tracks your recruitment and drives traffic to the site using social media
- Example of an ad
 - <https://studypages.com/s/angi-anorexia-nervosa-genetics-initiative-918724/?donottrack=1>

Community Engagement

- Community engagement is essential to increasing diversity in research participation to determine effective treatments and prevention strategies for populations most adversely impacted by health inequalities
- Connects investigators with local coalitions and community based organization
- Start early in the research process

Community Engagement

- Some principles to think about when engaging in community partnerships
 - It's all about building relationships
 - Do “With” - Not “For” or “To”
 - Be responsive to community partners' priorities and perspectives
 - Plan if possible for a long term engagement
 - Mutual benefit and respect
 - Share findings with the groups that help
 - Collaborative from start to finish

Recruiting underserved populations

- Improving recruitment
 - Raise awareness through outreach programs
 - Target publicity campaign to group of interest
 - Find out why they do not want to participate
 - Use incentives such as
 - financial compensation
 - therapeutic interventions
 - provision of health services
 - provision of transportation services to facilitate participation

Retention

- Focus on retention must start early
- Evaluate protocol for difficulties
 - Look at pressure points for gaps in schedule
 - Identify places in study schedule where participants may experience more stress, lose interest, need extra info, encouragement or support
 - Consolidate visits where you
 - Don't make any one visit too heavy
- Avoid large gaps between study contacts

Think about the place where participants are engaged.

- Look at staffing/facility needs
- What can be done on site or off site
- Create comfortable atmosphere; physically appealing clinic with parking aplenty
- Provide a map
- Tell to bring a book if there will be down time; clarify expected wait times
- Water cooler, Wi-Fi, magazines
- Create clear consistent pattern of appointments (same room, same start and end times)
- If participants are coming in for fasting blood draws don't drink coffee in front of them and have snacks for afterwards
- Keep communication open (hotline, email, website, social media)

Recognize when subjects may be ready to flee

- Missed appointments
- Unreturned phone calls
- Complaints about procedures
- Too busy to schedule appointments
- Lack of enthusiasm

Methods to Enhance Retention

- Offer convenient physical access and appointment times
 - Take into account vacations, school breaks, holidays
- Frequent communication
 - Send newsletter
 - Provide written or telephone contacts between visits
 - Remember special occasions
- Maintain contact with PCP (If applicable)
- Assist with transportation
- Compensation
 - Bonuses at key time points
- Sympathize with problems
- Respond to complaints

Finding participants lost to follow-up

- Ask each participant to provide name and address of an individual who does not live with them, but likely to know their whereabouts
- Obtain multiple emails
- Obtain multiple phone numbers
- Use postal service to get change of address
- Use certified letters
- Use detective service

- Keep track of why people drop out so you can improve recruitment and retention for the next study or make changes to the current study

Example of one study's retention strategy

- **Alternative contact numbers** were requested at the baseline assessment and rechecked throughout the study.
- The study protocol called for at least **10 call attempts** to be made per participant per contact at varying times of the day and days of the week, including evenings and weekends.
- Study staff repeatedly **checked** the clinic database and patient charts for **updated phone numbers** to replace disconnected or wrong numbers and made repeated attempts to re-contact participants who left the country for months at a time.
- To **alleviate transportation difficulties** for patients getting to the clinic for intervention visits, and for those who 'no-showed' multiple times, home visits were conducted.
- **Wide time windows** of 4–6 weeks were instituted around each contact point to allow for the greatest possibility of reaching participants.
- Participants still not reached after these efforts were **discussed in study team meetings** on a case-by-case basis to ensure that all possible avenues for reaching them had been explored.

Resources

Accrualnet

- <https://accrualnet.cancer.gov/>

Clinical performance partners

- <http://www.clinicalperformancepartners.com/downloadable-tools-templates.php>

Center for Information and Study on Clinical Research Participation

- <http://www.ciscrp.org/>



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