Recruitment and Retention Plan – Source Document
SITE FEASIBILITY AND PLANNING

Effective participant recruitment is vital to the success of clinical trials. A detailed recruitment and retention plan for each site will help ensure a well-qualified recruitment team, specific strategies for recruitment and retention, evaluation and an adequate budget and resources to implement the work. This template is intended to enhance participant recruitment and maximize retention.

Briefly describe the study and primary aims. Please reference section in primary document if available.

1. STUDY POPULATION

Briefly describe the population(s) being recruited for this study site.

A. This is a study of *(men, women, adults, children)* who _____ *(have X condition/ are at risk for X/ are from X demographic/ are healthy participants).* A total of _____ participants will be recruited and participation will entail _____ *(briefly describe participant activities, # visits, etc.)*

B. Describe why someone would want to participate in this study. What is the value of participation to the study participant?

C. The study population at this site is likely to communicate in which language(s)?

_____ English   _____ Spanish   _____ Other (describe):

TABLE I. Study inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria

2. STUDY SETTING

A. This study is (check all that apply): ☐ In-patient ☐ Out-patient ☐ Community-based/Online

B. Participants to be enrolled at this site: _____

Table II. Enter the name of each location where participants may be recruited, consented, or enrolled. Please add rows to the table as needed.

Site Name	Will recruitment take place at more than one location at this site? (yes/no)	Provide the name of each recruiting location for the site (if applicable).

3. EVIDENCE OF RECRUITMENT FEASIBILITY

A. Describe and attach evidence of support of population availability and accessibility for this site. *(EHR search results, registries, longitudinal studies, past participation).*

B. Provide evidence of support for accessibility for this site *(letters of commitment from community leaders, sites, and primary care physicians).*

C. Provide evidence of prior recruitment success in this population and/or setting.

D. Are there competing studies at this site? Yes/No

   If yes, describe the competing studies at this study site, how competing studies might affect recruitment and the plan for overcoming this barrier.

   Describe how collaboration with the recruitment and retention teams of competing studies will occur to establish mechanisms for referrals and foster team science.

TABLE III: Study population barriers and solutions. Describe barriers related to availability, accessibility and eligibility criteria and the plan for overcoming barriers.

Potential Barrier	Type of Barrier (Availability, Accessibility, Eligibility Criteria)	Solutions: Describe actions you will take to overcome barriers.	Person responsible for plan execution

4. RECRUITMENT AND RETENTION TEAM

TABLE IV. Team Member Task Delegation. List each recruitment and retention team member at this site by role, including community members and participants, role qualifications to recruit for this study and indicate for what tasks each is responsible.

	Qualifications	% Effort for R&R	Communication	(Pre) Screening	Consenting	Enrollment	Monitoring	Evaluating	Retention	Study Conduct	Return of Results
PI/Co-PI											
Study Coordinator											
Community Member(s)											
(Add rows as needed)											

A. Describe the study-specific training available to recruitment personnel at this site *prior to enrollment* and throughout the recruitment phase to ensure consistency across sites. Include how the training will be documented.

B. Describe the recruitment and retention team's experience recruiting and retaining the study population. If no experience, describe how your team will acquire the necessary skills.

C. Describe the recruitment team's experience recruiting and retaining underrepresented racial and ethnic minorities and other vulnerable populations. If no experience, describe how your team will acquire the necessary skills/cultural competencies.

D. Describe how the effectiveness of recruitment and retention team training will be measured and evaluated.

E. Describe how turnover in recruitment and retention team personnel will be handled in order to minimize a delay in recruitment.

F. Describe how changes to the study protocol including eligibility criteria or additional or unexpected training will be recommended, approved, recorded and communicated to the recruitment and retention team.

G. Describe how priority stakeholders *(i.e. community members, patients, primary care physicians, potential participants and their families)* were or will be involved in the development of the site-specific recruitment strategy (if applicable).

5. RECRUITMENT METHODS

A. Indicate which **recruitment** methods will be used at this site.

		Physician Letter		Radio	
Printed brochure		Investigator Letter		TV	
Post Cards		Community Leader Letter		Newspaper	
Business Cards		Phone Calls		Magazine	
Newsletters		Text Messages		Other print media	
Referral Cards		Public Service Announcement		Video/YouTube	
Digital Media (expand for types)		Physician Referral		Study Website	
Email		Friend/Family Referral		Other Website	
Thank you note/letter		Health Fair/Community Event		Search engine optimization	
Apps		Registries (local)		Registries (national)	
Electronic health records, databases		Describe "Other"			

B. Using the stages of recruitment outlined below as a guide, describe how each recruitment method indicated in the table above will be used for participant recruitment. Indicate which methods are primary and which are back up plans if recruitment rates are low. Finally, describe how the success of each recruitment method will be measured.

     i.   Awareness

     ii.   Pre-Screening/Screening

      iii.   Consenting

      iv.   Enrollment

C. Describe who will be responsible for overall recruitment and retention at this site and how, to whom and with what frequency enrollment status will be reported to the coordinating center.

D. Describe activities to ensure the enrollment of underrepresented racial and ethnic minorities and other vulnerable populations. Include who will be responsible for execution of these activities.

E. If applicable, describe the use of incentives, compensation, reimbursement of costs, etc.

6. RETENTION METHODS

A. Indicate which **retention** methods will be used at this site:

Phone calls		Newsletters		Reporting results	
Email		Study Updates		In-person meetings	
Reminder cards		Social Media		Connections to groups or resources	
Text Messages		Apps		Holiday/Birthday/Thank you cards	
Notes to provider		Community events/ updates through community partners		Return of health information	
Return of non-health related information		Calendars		Childcare	
Educational sessions		Transportation		Other (please describe)	

B. Describe how each retention method indicated above will be used to retain participants in the study.

C. Describe how the recruitment and retention team will build rapport with participants. Include any activities designed to target a specific sub-group of participants.

D. Describe how, to whom and with what frequency participant attrition and missed visits will be reported at each site.

7. COMMUNICATION PLAN

A. Describe how recruitment and retention team communication will be maintained within the site throughout the study? How will issues be handled?

B. Describe how, by whom and to whom recruitment and retention issues or concerns will be communicated to the coordinating center.

C. Describe how study progress, mid-study results and final results will be conveyed to participants

8. RECRUITMENT AND RETENTION TIMELINE

A. Describe the timeline and process for site initiation.

B. Describe the risk(s) of slow study start-up at this site on enrollment and overall study timeline. Provide solutions for preventing risks and/or overcoming slow study start-up.

C. Describe/define "trigger" points for intervention including who will be contacted for assistance with recruitment if enrollment at this site falls below expected goals.

A. What are the "trigger" points for <u>early termination</u> of the study at this site due to poor enrollment/attrition?

TABLE V. Site-specific Enrollment Timeline and Milestones.

Group/Site/Arm	Date recruitment begins (R)	Time Recruitment Begins to First Enrolled (R+days)	# of Participants Enrolled before R+60	50% participants enrolled (R+days)	Date Enrollment Complete (R+Days)

9. EVALUATION

A. Describe how the recruitment and retention plan will be evaluated *(who, what, when, how).*

B. Describe how participant engagement and satisfaction will be monitored and evaluated throughout the course of the study *(who, what, when and how)*.

C. How will participant engagement and satisfaction for participants who drop out of the study be monitored and evaluated *(who, what, when and how)?*

10. BUDGET

Describe how the budget was developed to ensure availability of resources for adequate personnel, recruitment and retention methods, evaluation and participant compensation.

TABLE VI. Recruitment and Retention Budget Considerations

Expense	Description	Allocation
Recruitment/Retention Team		$
Incentives		$
Recruitment Activities		$
Retention Activities		$
Training		$
Postage		$
Feasibility		$
Compensation		$
Phone		$
Reimbursements		$

Other		$
Other		$
	Total:	**$ 0**

Glossary

STUDY POPULATION

Study Population – the population meeting all inclusion and exclusion criteria

Participants – individuals who consent and are enrolled in the study.

STUDY SETTING - the location of study enrollment and/or study activities.

In-Patient – Participants will be enrolled and/or complete research activities in an in-patient setting.

Out-Patient – Participants will be enrolled and/or complete research activities in an out-patient clinical setting.

Community-based – participants will be enrolled and/or complete research activities outside of a clinical setting.

Study Sites – An institution/Co-PI receiving funding to carry-out all aspects of a research participation

Enrolling Sites – under the supervision of a study site, any location that will consent and enroll study participants. A location may be both a study site and an enrolling site, but not all enrolling sites will be independent study sites. Study sites may have multiple enrolling sites such as clinics, support groups and churches.

EVIDENCE OF RECRUITMENT FEASIBILITY

Population Availability – documentation that the target study population exists

Population Accessibility – documentation that you have been granted access to inform and engage the population in research activities

Evidence of Support – documentation that recruiting locations will allow their patients, members, contacts to be informed and enrolled in the research study such as a letter of support from church leadership

Evidence of prior recruitment success – pilot study data, published manuscripts indicating success recruitment with a similar target population and similar enrolling sites.

Competing Studies – any study actively recruiting or preparing to recruit a similar study population and/or recruiting participants from the same enrolling sites.

Population Barriers – any reason why the study team may have difficulty engaging and/or enrolling the target study population.

Population solutions – how the study team will predict and minimize or resolve barriers to the study population.

RECRUITMENT AND RETENTION TEAM

Team Member/Role - any individual who will participate in the identification and communication with potential and/or active study participants. This includes any individual participating in website design, engagement pieces, newsletters, printed materials, public speaking, radio, networking, and the consenting, screening, enrolling, monitoring, evaluating, retaining and returning of results to study participants.

Qualifications to recruit – For a team member, the experience indicating this individual is capable of contributing to the successful enrollment of participants for this particular study. For a role, the skills required for successful contribution to the recruitment and retention team.

Effort on this project – the percent of time an individual or study role has agreed to engage or is expected to be engaged in tasks related specifically to this study.

Task delegation – indicate using a check mark the assigned or expected tasks of each team member/role. Check all that apply.

Communication – engaged in any direct or indirect communication with the study population including written, verbal and electronic. Most recruitment and retention team members will communicate with study participants and/or legal guardians.

Screening – engaged in reviewing eligibility criteria for potential study participants.

Consenting – engaged in reviewing the consent form, responding to questions and obtaining consent from study participants.

Enrollment – engaged in preparing participants files, setting appointments, ordering participant drug/device, reviewing study procedure and timelines and any other initial participant tasks.

Monitoring – engaged in reviewing, recording and reporting screening, enrollment and retention of study participants throughout the course of the study.

Evaluation – engaged in reviewing, recording and reporting the use and effectiveness of recruitment and retention activities.

Retention – responsible for implementing retention activities

Study Conduct – engaged in the education and training of recruitment and retention team members in regards to participant engagement

Return of Results – engaged in providing study participants with study results, resources or other relevant information

Stakeholders – any individual that can or will be influenced or impacted by this study. This includes but is not limited to the target study population and their parents, siblings, friends, pharmacy employees, teachers, community leaders, religious leaders, primary care providers, medical specialists, caregivers, etc.

RECRUITMENT ACTIVITIES

Awareness – all activities used with the intent of communicating and educating stakeholders about the study.

Screening – activities specific to the task of identifying potential participants

Consenting – activities specific to informing potential participants about the details of the study and obtaining consent/assent

Enrollment – activities to welcome and record new study participants

Primary activities – activities that will implemented for ALL study participants

Back up plans for recruitment – activities that will implemented only if recruitment goals are not being met

RETENTION ACTIVITIES

Rapport – a trusting relationship between study team member and a study participant

Participant attrition – the percentage of participants who formally drop out of the study or fail to return to study visits divided by the total number of enrolled study participants.

Preliminary study results – study participation findings from either an individual or total study population that can be shared with study participants prior to the conclusion of the study/final data set.

COMMUNICATION PLAN

All phases of the study – awareness, screening, consenting, enrolling, retention

RECRUITMENT AND RETENTION TIMELINE

Site initiation – the process of arriving at a point in time when a study site is cleared to begin enrollment at one or more enrollment sites.

Slow study start up – none or few participants enrolled within a pre-defined time period of the date of site initiation.

Study timeline – the time from when a study is cleared to recruit participants until the final participant has completed all study activities.

Trigger points – the point at which enrollment falls below a specified rate or total and is unlikely to recover within the time frame of the study.

Intervention – a strategy where resources outside of the recruitment and retention team are engaged in an effort to salvage study enrollment.

Date recruitment begins – first day that a study team is cleared to begin recruitment

Date enrollment will be complete – date that the last participant is enrolled in the study

EVALUATION

Participant engagement – maintaining contact to ensure interest and eagerness in full participation.

Participant satisfaction – participant benefit vs. participant burden

BUDGET

Availability of resources – how the activities and personnel described in this recruitment and retention plan will be funded

Adequate personnel – personnel with the time and skills required to successfully recruit participants for this study