**Recruitment and Retention Plan – Source Document**

**COORDINATING CENTERS**

Effective participant recruitment is vital to the success of clinical trials. A detailed recruitment and retention plan for the coordinating center will help ensure sites have a well-qualified recruitment team, specific strategies for recruitment and retention, 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 applicable section(s) in primary document if available.

## 1. STUDY POPULATION

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

1. 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*.)
2. Describe why someone would want to participate in this study. What is the value of participation to the study participant?
3. The study population 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

1. This study is (check all that apply):  In-patient  Out-patient Community-based/Online
2. Total number of study sites: \_\_\_\_\_\_\_
3. Participants to be enrolled at each site: \_\_\_\_\_\_\_\_

Table II. Enter the name of each enrolling site.

|  |  |  |
| --- | --- | --- |
| ****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

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

1. Provide evidence of support for accessibility for each site *(letters of commitment from community leaders, sites, and primary care physicians).*
2. Provide evidence of the coordinating center’s prior recruitment success in this population and/or setting.
3. Are there competing studies at this/any site? Yes/No

*If yes, describe the competing studies at each 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**** | ****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 coordinating center recruitment and retention team member by role, including community members and participants, role qualifications to recruit for this study and indicate for what tasks each is responsible.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Team Member/Role | 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) |  |  |  |  |  |  |  |  |  |  |  |

1. Describe the study-specific training available to recruitment personnel *prior to enrollment* and throughout the recruitment phase to ensure consistency across sites. Include how the training will be documented. *If multiple sites, include plans for training at each site*
2. Describe the coordinating center’s recruitment and retention team’s experience recruiting and retaining the study population. If no experience, describe how your team will acquire the necessary skills.
3. Describe the coordinating center’s 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.
4. Describe how the effectiveness of recruitment and retention team training will be measured and evaluated.
5. Describe how turnover in recruitment and retention team personnel will be handled in order to minimize a delay in recruitment.
6. Describe how changes to study protocol including eligibility criteria or unexpected add-on training will be recommended, approved, recorded and communicated to the recruitment and retention team. Include plans for communication across multiple sites if applicable.
7. 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 recruitment strategy (if applicable).

## 5. RECRUITMENT METHODS

1. Indicate which **recruitment** methods will be used.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Printed 1-page flyer |  | 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” | | | |

1. 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.
2. Awareness
3. Pre-Screening/Screening
4. Consenting
5. Enrollment
6. Describe who will be responsible for overall recruitment and retention across sites and how, to whom and with what frequency enrollment status will be reported at each site.
7. 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.
8. If applicable, describe the use of incentives, compensation, reimbursement of costs, etc.

## 6. RETENTION METHODS

1. Indicate which **retention** methods will be used:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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) |  |
| Patient-Facing Study Calendar of Events (create template) |  |  |  |  |  |

1. Describe how each retention method indicated above will be used to retain participants in the study.
2. Describe how the coordinating center’s recruitment and retention team will build rapport with study **participants**. Include any activities designed to target a specific sub-group of participants.
3. Describe how the coordinating center’s recruitment and retention team will build rapport with study **sites**.
4. Describe how, to whom and with what frequency participant attrition and missed visits will be reported at each site.
5. Will study results (preliminary and/or final) be available for dissemination to participants?

*If yes, describe how and when results will be disseminated.*

## 7. COMMUNICATION PLAN

1. Describe how recruitment and retention team communication will be maintained throughout the study? How will issues be handled? *If multi-site or multi locations, how will continuous communication be maintained across sites?*
2. Describe how study progress and results will be conveyed to study participants.
3. Describe how study progress and results will be conveyed to sites.

## 8. RECRUITMENT AND RETENTION TIMELINE

1. Describe the timeline and process for site initiation including the number of sites that can be initiated at one time.
2. Describe the risk(s) of slow study start-up on enrollment and overall study timeline. Provide solutions for preventing risks and/or overcoming slow study start-up.
3. Describe/define “trigger” points for intervention at a study site including who will be contacted for assistance with recruitment if enrollment falls below expected goals.
4. What are the “trigger” points for early termination of a study site due to poor enrollment/attrition?
5. What are the “trigger” points for early termination of the study due to poor enrollment/attrition?
6. 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

1. Describe how the recruitment and retention plan will be evaluated *(who, what, when, how).*
2. Describe how participant engagement and satisfaction will be monitored and evaluated throughout the course of the study *(who, what, when and how*).
3. 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 tools, evaluation and participant compensation.

TABLE VI. Recruitment and Retention Budget Considerations

|  |  |  |
| --- | --- | --- |
| Resource | 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