# **Recruitment and Retention Plan – Source Document**

# Effective participant recruitment is vital to the success of clinical trials. A detailed recruitment and retention plan will help ensure studies 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 section in primary document if available.

# Study population

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

1. This is a study of (*men, women, adults, children*) who \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. A total of \_\_\_\_\_\_\_ participants will be recruited and participation will entail

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(*briefly describe participant activities, # visits, etc.*)

1. Describe the return of value for participants and community stakeholders

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## *Table I. Study inclusion and exclusion criteria*.

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| Inclusion Criteria | Exclusion Criteria |
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# Study setting

1. This study is (check all that apply):  In-patient  Out-patient  Community-based
2. Total number of study sites: \_\_\_\_\_\_\_\_\_\_

## *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). |
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# 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)*.

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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 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.*

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

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## *Table III: Study population barriers and solutions. Describe barriers related to availability, accessibility and eligibility criteria and the plan for overcoming barriers. (i.e. subject-related barriers, investigator-related barriers, protocol-related barriers and “other” barriers).*

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| --- | --- | --- | --- |
| Potential Barrier | Type of Barrier  (Availability, Accessibility, Eligibility Criteria) | Solutions: Describe actions you will take to overcome barriers. | Person responsible for plan execution |
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# Recruitment and retention team

## *Table IV. Team Member Task Delegation. List each 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.*

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| *Team Member/Role* | *Qualifications* | *% Effort* | *Communication* | *Screening* | *Consenting* | *Enrollment* | *Monitoring* | *Evaluating* | *Retention* | *Study Conduct* | *Return of Results* |
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1. Describe the study-specific training available to recruitment personnel prior to enrollment and throughout the recruitment phase. Include how the training will be documented. If multiple sites, include plans for training at each site

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1. 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.

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1. 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.

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

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

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1. 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.

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1. Describe how stakeholders (i.e. community members, patients, primary care physicians, potential participants and their families) were or will be involved in study design (if applicable).

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# Recruitment activities

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

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| --- | --- | --- | --- | --- | --- |
| 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 |  |
| Social 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. Describe the strategies and activities that will be used in each stage of recruitment below. Indicate which activities are primary and which are back up plans if recruitment rates are low. Include in each stage how recruitment activity data will be captured in real time for later evaluation.
   1. Awareness \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. Screening \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. Consenting \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* 1. Enrollment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. 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.

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1. 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

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

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# Retention activities

1. Indicate which retention activities will be used:

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| --- | --- | --- | --- | --- | --- |
| Phone calls |  | Newsletters |  | Return of results |  |
| Email |  | Study Updates |  | In-person meetings |  |
| Reminder cards |  | Social Media |  | Connections to groups or resources |  |
| Text Messages |  | Apps |  | Holiday cards/Birthday cards |  |
| Notes to provider |  | Community events/ updates through community partners |  | Return of health information |  |
| Return of non-health related information |  | Calendars |  | Letters to participants |  |
| Educational sessions |  | Describe “Other” | | | | |

1. Describe how the recruitment and retention team will build rapport with participants.

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1. Describe the strategies and activities that will be used to retain participants in the study.

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

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1. Will preliminary study results be available for dissemination to participants?

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

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# Communication plan

1. How will communication be maintained among recruitment and retention team members throughout all phases of the study? *If multi-site or multi locations, how will continuous communication be maintained across sites?*

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1. How will communication problems that arise during the course of the study be documented and resolved?

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1. Describe how return of value will be conveyed to participants

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# 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.

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1. Describe the risk(s) of slow study start-up on enrollment and overall study timeline and solutions for preventing risks and/or overcoming obstacles.

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1. Describe/define “trigger” points for intervention including who will be contacted for assistance with recruitment if enrollment falls below expected goals.

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1. What are the “trigger” points for early termination of the study due to poor enrollment/attrition?

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## *Table V. Enrollment Timeline and Milestones.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Group/Site/Arm** | **Date recruitment begins (mm/yy)** | **Time Recruitment Begins to First Enrolled (days)** | **50% participants enrolled (mm/yy)** | **Date Enrollment Completes (mm/yy)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Evaluation

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

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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# 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. Itemized Budget.**

|  |  |  |
| --- | --- | --- |
| Expense | Description | Budget |
| Recruitment/Retention Team |  | $ |
| Incentives |  | $ |
| Recruitment Activities |  | $ |
| Retention Activities |  | $ |
| Training |  | $ |
| Postage |  | $ |
| Feasibility |  | $ |
| Compensation |  | $ |
| Phone |  | $ |
| Reimbursements |  | $ |
| Other |  | $ |
| Other |  | $ |
| Total: | | **$ 0** |