Recruitment Feasibility Worksheet

Use this checklist when conducting a recruitment feasibility assessment.

Complete the Benefits, Strategies, and Tactics sections for your recruitment plan.

|  |
| --- |
| **Study Indication** |
| What is the therapeutic area or population that you will recruit? |  |
| **Protocol Objectives** |
|  | **Yes** | **No** | **Comments** |
| Have protocol objectives (primary and secondary) been defined and are they clear? | [ ]  | [ ]  |  |
| **Protocol Organization** |
|  | **Yes** | **No** | **Comments** |
| Are the inclusion criteria clear? | [ ]  | [ ]  |  |
| Are the exclusion criteria clear? | [ ]  | [ ]  |  |
| Does the procedures and timeline chart (Time and Events Table) match the protocol? | [ ]  | [ ]  |  |
| **Target Population Characterization** |
|  | **Yes** | **No** | **Comments** |
| Has a biostatistician consult to determine sample size been obtained | [ ]  | [ ]  |  |
| Has a calculation been performed to estimate screening vs. enrolled subjects?  | [ ]  | [ ]  |  |
| Will you recruit from your own patient population? | [ ]  | [ ]  |  |
| How many patients in your database meet the basic inclusion/exclusion criteria? | [ ]  | [ ]  |  |
| If recruiting from the community, how many people in your immediate geographic area meet the inclusion/exclusion criteria? | [ ]  | [ ]  |  |
| Have you identified benefits for volunteers? | [ ]  | [ ]  |  |
| Have you identified barriers for volunteers? | [ ]  | [ ]  |  |
| Where do your potential volunteers live, work, shop and conduct daily activities? | [ ]  | [ ]  |  |
| Will conducting a multi-center trial be more feasible to recruit the subjects you need | [ ]  | [ ]  |  |
| **Study Timelines** |
|  | **Yes** | **No** | **Comments** |
| Calculate your total enrollment per year/month/week/day. Did you allow for slow enrollment times like holiday and vacation periods?  | [ ]  | [ ]  |  |
| Have you created a mock study visit cascade? Do staff resources match? | [ ]  | [ ]  |  |
| Do you have a plan for scheduled or unexpected staff absences? | [ ]  | [ ]  |  |
| Have interdependencies between other timelines been identified? | [ ]  | [ ]  |  |
| **Budget Considerations** |
|  | **Yes** | **No** | **Comments** |
| Do you have a recruitment budget? | [ ]  | [ ]  |  |
| Are screening costs included?  | [ ]  | [ ]  |  |
| Have you considered reasonable subject compensation? | [ ]  | [ ]  |  |
| Have you reviewed the time and events budget table with the protocol? | [ ]  | [ ]  |  |
| Has a recruitment deadline (completion date) been established? | [ ]  | [ ]  |  |

**Recruitment Barriers and Risk Management Plan**

List barriers to recruitment based on the protocol and proposed ways to manage them.

|  |  |  |
| --- | --- | --- |
|  | **Barriers** | **Management Plan** |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |
| 7 |  |  |
| 8 |  |  |
| 9 |  |  |
| 10 |  |  |

**Recruitment Benefits and Promotional Plan**

List benefits that volunteers will get by participating in this study and use in promotional materials.

|  |  |  |
| --- | --- | --- |
|  | **Benefits** | **Promotion Plan** |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |
| 5 |  |  |
| 6 |  |  |
| 7 |  |  |
| 8 |  |  |

**Your Proposed Recruitment Strategies** (for example: Adults from the local community)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Strategies** | **Start/Stop Date** | **Process Owner** | **Cost** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

 **Your Proposed Recruitment Advertisements** (for example: Ad in Durham Herald newspaper, flyers posted on Franklin Street kiosks)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Advertisements** | **Start/Stop Date** | **Process Owner** | **Cost** |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |

**Notes**