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Recruitment Contract and Budget Review

**Protocol Name:   
Principal Investigator:   
Project Sponsor:   
Project Coordinator/Administrator:   
Review Date:**

| **Study Indication** | | | | |
| --- | --- | --- | --- | --- |
| Therapeutic Area or Population | |  | | |
| **Protocol Objectives** | | | | |
|  | **Yes** | | **No** | **Look out for** |
| Have protocol objectives (primary and secondary) been defined and are they clear? |  | |  | How many data points will be monitored and how frequently |
| **Protocol Requirements** | | | | |
|  | **Yes** | | **No** | **Look out for** |
| Does the procedures and timeline chart (Time and Events Table) match the protocol? |  | |  | Missing procedures in the time and events table |
| Are adverse events defined? |  | |  | Estimated # of SAEs and cost |
| Will screen fails be allowed to rescreen? |  | |  | Determine screening time and add to budget |
| Are early terminations defined? |  | |  | Lost revenue if not compensated |
| **Study Timelines** | | | | |
|  | **Yes** | | **No** | **Look out for** |
| Calculate your total enrollment per year/month/week/day. Did you allow for slow enrollment times like holiday and vacation periods? |  | |  | Management costs; chart review costs |
| Have resource risk mitigation strategies been defined? Has a contingency strategy been established? |  | |  | Have a back-up plan for staff vacations or unexpected illnesses |
| Have you created a mock study visit cascade? Do staff resources match? |  | |  | Do a walk-through of your recruitment process and time it |
| Have interdependencies between other timelines been identified? |  | |  | Consider any washout periods; time to receive lab results |
| **Budget Proposal** | | | | |
|  | **Yes** | | **No** | **Look out for** |
| Do you have a defined recruitment budget? |  | |  | Uncompensated visits or procedures |
| Do you have screening costs included? |  | |  | SFs add up! Negotiate! |
| Have you reviewed the time and events budget table with the protocol? |  | |  | Remember to include time, not just equipment expenses |
| **Budget Approval** |  | |  |  |
|  | **Yes** | | **No** | **Look out for** |
| Has the recruitment budget been approved? |  | |  | Amendments to the protocol after budget negotiation |
| Has a recruitment deadline (completion date) been established? |  | |  | Unrealistic timelines |
| Have interdependencies between other projects been identified? |  | |  | For example, enrollees in Phase II study are needed for the Phase III |
| **Project Estimates** |  | |  |  |
|  | **Yes** | | **No** | **Look out for** |
| Start date |  | |  | Not site initiation date, but start of prescreening |
| End date |  | |  | When all subjects at your site have completed the trial, not just when enrollment is complete |
| Effort in hours |  | |  | Be realistic |
| Total budget |  | |  | Include contingencies- higher than expected screen fail rate; protocol amendments |
| # Of staff |  | |  | Include ancillary staff such as phone screeners or administrative staff |
| # Of completed subjects |  | |  | Verify contract and budget match |