VCU Center for Clinical and Translational Research
Virginia Commonwealth University

Protocol Feasibility Checklist

Sponsor/Clinical Research Organization (CRO)

❑Yes ❑No Has your previous experience with this sponsor/CRO been satisfactory?

❑Yes ❑No If you have had no previous experience with this sponsor/CRO, does the sponsor's/CRO's reputation check out with colleagues?

Population

❑Yes ❑No Do you have access to the right patient population?

❑Yes ❑No Will you be able to recruit patients from internal sources?

❑Yes ❑No If not, will sponsor provide funding?

❑Yes ❑No Is the proposed enrollment goal realistic?

❑Yes ❑No Is the proposed enrollment period realistic?

❑Yes ❑No Will enrollment compete with other studies seeking the same patients?

❑Yes ❑No Are inclusion/exclusion criteria reasonable? (Consider the likely screen failure ratio and the number of screen failures for which the sponsor will pay.)

❑Yes ❑No Do you expect that the adverse event profile is reasonable? (Consider the health status of the population.)

Protocol

❑Yes ❑No Is the protocol well designed?

❑Yes ❑No Is the protocol ethical? (Or, will the IRB have concerns…)

❑Yes ❑No Is the study question important?

❑Yes ❑No Will the subjects benefit from participating in the study?

❑Yes ❑No Is the protocol in final form? If not, how many amendments can be expected before it is in final form? (Consider your time required to review each amendment.)

❑Yes ❑No Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written?

❑Yes ❑No Will coordination with other departments/services be required for study visits or procedures?

❑Yes ❑No Can other services (e.g., lab, radiology) meet the protocol requirements?

❑Yes ❑No Is necessary equipment available?

❑Yes ❑No Is this a Phase IIIb protocol? (Drop-outs may be more likely if the study drug becomes commercially available while the study is still underway.)

❑Yes ❑No Is the study of reasonable length in duration? (Drop-outs are more likely in long studies.)

❑Yes ❑No If an inpatient study and floor staff are needed, has this been cleared appropriately?

❑Yes ❑No Is patient compliance anticipated? (Consider additional time and expenses to monitor subjects' compliance with time-consuming phone calls or postcards)

❑Yes ❑No Are case report forms reasonable (not overly complex)?

❑Yes ❑No Is the number of case report forms per subject reasonable?

❑Yes ❑No Are drug or device storage/accountability requirements clearly defined and manageable?

❑Yes ❑No Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)

Procedures

❑Yes ❑No Are procedures carefully planned to avoid inconvenience, where possible?

❑Yes ❑No Are procedures not too difficult? (e.g., elderly patients asked to swallow large pills)

❑Yes ❑No Are procedures carefully considered to avoid pain?

❑Yes ❑No If subject diaries are used, will staff time for transcription or interpretation be available and covered by the sponsor?

❑Yes ❑No Is the dosing schedule reasonable (not overly complex)?

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Staff

❑Yes ❑No Is qualified staff available?
❑Yes ❑No If needed, is training available?
❑Yes ❑No Is the workload manageable?
❑Yes ❑No Does the PI have adequate time to devote to the protocol?
❑Yes ❑No If additional specialists needed, are these individuals prepared to participate?
❑Yes ❑No Is a draft consent form provided by the sponsor? (Staff-written consent forms take time.)
❑Yes ❑No Are study visits manageable given current scheduling environment? (Consider how many different study staff will subjects encounter in a given visit)
❑Yes ❑No Is projected query turnaround time workable?

Budgets

❑Yes ❑No Does sponsor's preliminary budget appear adequate?
❑Yes ❑No If sponsor contracts to pay for "evaluable" subjects, is the definition of an evaluable subject clear and acceptable?
❑Yes ❑No If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities, e.g., IRB submission, meetings, chart reviews?
❑Yes ❑No If not paying for a full-time coordinator, will sponsor pay for events that are difficult to budget in advance, such as:
❑Yes ❑No Protoctocol amendments (may require consent form revisions)?
❑Yes ❑No Reconsenting subjects?
❑Yes ❑No Unanticipated monitoring visits?
❑Yes ❑No Audits?
❑Yes ❑No Unexpectedly high number of SAEs?
❑Yes ❑No Will sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?
❑Yes ❑No Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?
❑Yes ❑No Will sponsor pay for study record storage?
❑Yes ❑No Will sponsor pay for informed consent translations?

Other

❑Yes ❑No Is adequate clinic and office space available?
❑Yes ❑No If the sponsor acknowledges that the study may be audited by the FDA, is extra time built into the budget for audit preparation? (FDA audits take staff time.)
❑Yes ❑No Will the sponsor provide additional time reimbursement for their own audit procedures (and is this acceptable)?
❑Yes ❑No Will electronic or remote data retrieval systems be used? If so, will sponsor provide training?
❑Yes ❑No Have you considered the sponsor's site monitor visit schedule? (Frequent visits will consume staff time but may help to minimize the number of data queries.)
❑Yes ❑No If the monitor needs to meet with the PI at every site visit, is this level of cost built into the budget?
❑Yes ❑No Is time spent at an Investigator meeting fully covered as a non-refundable start-up expense?