

PROTOCOL FEASIBILITY CHECKLIST

Factors to consider:

1. Sponsor/Clinical Research Organization (CRO)

	Has your previous experience with this sponsor/CRO been satisfactory?
	If you've had no previous experience with this sponsor/CRO, have you checked the sponsor/CRO's reputation with colleagues?
	Is the budget sufficient to cover costs?

2. Population

	Do you have access to the right patient population?
	Will you need to recruit patients from external sources? If so, will sponsor provide funding?
	Is the proposed enrollment goal realistic?
	Is the proposed enrollment period realistic?
	Will enrollment compete with other studies seeking the same patients?
	Are inclusion/exclusion criteria overly restrictive? (Consider the likely screen failure ratio and the number of screen failures for which the sponsor will pay.)
	Are vulnerable populations involved, e.g., children, impaired adults with special consent issues?
	Do you expect a significant number of adverse events? (How ill is this population?)

3. Protocol

	Is the protocol well designed?
	Is the protocol ethical? Will the IRB have problems with it?
	Does the standard of care of the protocol match the standard of care at the institution?
	Is the study question important?
	Will the subjects benefit from participating in the study?
	Is the protocol in final form? If not, how many amendments can be expected before it is in final form?
	Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written?
	Will coordination with other departments/services be required for study visits or procedures?
	Can other services (e.g., lab, radiology) meet the protocol requirements?
	Is necessary equipment available?
	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.)
	Is the study unusually long in duration? (Drop-outs are more likely in long studies.)
	If an inpatient study, will floor staff need to be involved?

	Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls or postcards?
	Are data collections forms complex?
	Is there a large number of case report forms per subject?
	Are drug or device storage/accountability requirements complicated?
	Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)

4. Procedures

	Are procedures frequent?
	Are procedures difficult, e.g., elderly patients asked to swallow pills?
	Are procedures painful?
	Are procedures inconvenient (causing subjects to miss work or school)?
	Are subject diaries used? If so, does this require staff time for transcription or interpretation?
	Is the dosing schedule complex?

5. Staff

	Are qualified staff available?
	If needed, is training available?
	Is the workload manageable?
	Does the PI have adequate time to devote to the protocol?
	Are additional specialists needed?
	Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff will subjects encounter in a given visit?
	Is projected query turnaround time workable?
	Can the clinical staff perform the protocol assessments required?

6. Space

	Is there space for staff?
	Is there space for supplies/equipment?
	Where will the subjects be seen? Is this accessible to the study population?
	Can the protocol assessments be compliantly conducted in the space available? If in the clinic, can the duration of the visits be accommodated?

6. Budgets

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	Does sponsor's preliminary budget appear adequate?
	If sponsor contracts to pay for "evaluable" subjects, is the definition of an evaluable subject clear and acceptable?
	If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities, e.g., IRB submission, meetings, chart reviews?
	If not paying for a full-time coordinator, will sponsor pay for events that are difficult to budget in advance, such as:
	<ul style="list-style-type: none">• Protocol amendments (may require consent form revisions)?
	<ul style="list-style-type: none">• Reconsenting subjects?
	<ul style="list-style-type: none">• Unanticipated monitoring visits?
	<ul style="list-style-type: none">• Audits?
	<ul style="list-style-type: none">• Unexpectedly high number of SAEs?
	Will sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?
	Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?
	Will sponsor pay for study record storage?
	Will sponsor pay for informed consent translations?

7. Other

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	Is adequate clinic and office space available?
	Does the sponsor expect this study to be audited by the FDA? (FDA audits take staff time.)
	Does the sponsor expect to audit this study (also time-consuming)?
	Will electronic or remote data retrieval systems be used? If so, will sponsor provide training?
	Will sponsor's site monitors visit frequently? (Frequent visits will consume staff time but may help to minimize the number of data queries.)
	Will the monitor need to meet with the PI at every visit?