

Protocol Feasibility Checklist-Cooperative Group Sponsored Study

1. Population

<input type="checkbox"/>	Do you have access to the right patient population?
<input type="checkbox"/>	Will enrollment compete with other studies seeking the same patients?
<input type="checkbox"/>	Are inclusion/exclusion criteria overly restrictive? (Consider the likely screen failure ratio and the number of screen failures for which the sponsor will pay.)

2. Protocol

<input type="checkbox"/>	Is the study question important?
<input type="checkbox"/>	Will the subjects benefit from participating in the study?
<input type="checkbox"/>	Will coordination with other departments/services be required for study visits or procedures (specimen submission, etc.)?
<input type="checkbox"/>	Will the study require the patient to be accrued to other studies (e.g. tissue depository)?
<input type="checkbox"/>	Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls or postcards?

3. Procedures

<input type="checkbox"/>	Are procedures frequent?
<input type="checkbox"/>	Are procedures difficult, e.g., elderly patients asked to swallow pills, repeated biopsies, etc.
<input type="checkbox"/>	Is the dosing schedule complex?

4. Staff

<input type="checkbox"/>	Does the PI have adequate time to devote to the protocol?
<input type="checkbox"/>	Are additional specialists needed?