

Budget Feasibility Checklist

<input type="checkbox"/>	Does sponsor's preliminary budget appear adequate?
<input type="checkbox"/>	If sponsor contracts to pay for "evaluable" subjects, is the definition of an evaluable subject clear and acceptable?
<input type="checkbox"/>	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:
<input type="checkbox"/>	<ul style="list-style-type: none"> • Protocol amendments (may require consent form revisions)?
<input type="checkbox"/>	<ul style="list-style-type: none"> • Reconsenting subjects?
<input type="checkbox"/>	<ul style="list-style-type: none"> • Unanticipated monitoring visits?
<input type="checkbox"/>	<ul style="list-style-type: none"> • Audits?
<input type="checkbox"/>	<ul style="list-style-type: none"> • Unexpectedly high number of SAEs?
<input type="checkbox"/>	Will sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?
<input type="checkbox"/>	Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?
<input type="checkbox"/>	Will sponsor pay for study record storage?
<input type="checkbox"/>	Will sponsor pay for informed consent translations?