### PRESTUDY CHECKLIST
A Self-Study Guide to Help Determine Feasibility of Doing Clinical Trial

#### 1. Sponsor/Clinical Research Organization (CRO)

<table>
<thead>
<tr>
<th>Question</th>
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<tbody>
<tr>
<td>Has your previous experience with this sponsor/CRO been satisfactory?</td>
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<tr>
<td>If you've had no previous experience with this sponsor/CRO, have you checked the sponsor/CRO's reputation with colleagues?</td>
</tr>
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#### 2. Population

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

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Is the protocol well designed?</td>
</tr>
<tr>
<td>Is the protocol ethical? Will the IRB have problems with it?</td>
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<tr>
<td>Is the study question important?</td>
</tr>
<tr>
<td>Will the subjects benefit from participating in the study?</td>
</tr>
<tr>
<td>Is the protocol in final form? If not, how many amendments can be expected before it is in final form?</td>
</tr>
<tr>
<td>Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written?</td>
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<tr>
<td>Will coordination with other departments/services be required for study visits or procedures?</td>
</tr>
<tr>
<td>Can other services (e.g., lab, radiology) meet the protocol requirements?</td>
</tr>
<tr>
<td>Is necessary equipment available?</td>
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<tr>
<td>Is this a Phase IIIB protocol? (Dropouts may be more likely if the study drug becomes commercially available while the study is still underway.)</td>
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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Is the study unusually long in duration? (Dropouts are more likely in long studies.)</td>
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<tr>
<td>If an inpatient study, will floor staff need to be involved?</td>
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<tr>
<td>Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls or postcards?</td>
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<tr>
<td>Are case report forms complex?</td>
<td></td>
</tr>
<tr>
<td>Is there a large number of case report forms per subject?</td>
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<tr>
<td>Are drug or device storage/accountability requirements complicated?</td>
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<tr>
<td>Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)</td>
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**4. Procedures**

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<tr>
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<tbody>
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<td>Are procedures frequent?</td>
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<td>Are procedures difficult?</td>
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<tr>
<td>Are procedures painful?</td>
<td></td>
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<tr>
<td>Are procedures inconvenient (causing subjects to miss work or school)?</td>
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<tr>
<td>Are subject diaries used? If so, does this require staff time for transcription or interpretation?</td>
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<tr>
<td>Is the dosing schedule complex?</td>
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**5. Staff**

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<thead>
<tr>
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<tbody>
<tr>
<td>Is qualified staff available?</td>
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<td>If needed, is training available?</td>
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<td>Is the workload manageable?</td>
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<tr>
<td>Does the PI have adequate time to devote to the protocol?</td>
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<tr>
<td>Are additional specialists needed?</td>
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<tr>
<td>Is a draft consent form provided by the sponsor? (Staff-written consent forms take time.)</td>
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<tr>
<td>Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff will subjects encounter in a given visit?</td>
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<tr>
<td>Is projected query turnaround time workable?</td>
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6. Budgets

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<tr>
<td>Does sponsor’s preliminary budget appear adequate?</td>
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<tr>
<td>If sponsor contracts to pay for &quot;evaluable&quot; subjects, is the definition of an evaluable subject clear and acceptable?</td>
</tr>
<tr>
<td>If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities, e.g., IRB submissions, meetings, chart reviews?</td>
</tr>
<tr>
<td>If not paying for a full-time coordinator, will sponsor pay for events that are difficult to budget in advance, such as:</td>
</tr>
<tr>
<td>• Protocol amendments (may require consent form revisions)?</td>
</tr>
<tr>
<td>• Reconsenting subjects?</td>
</tr>
<tr>
<td>• Unanticipated monitoring visits?</td>
</tr>
<tr>
<td>• Audits?</td>
</tr>
<tr>
<td>• Unexpectedly high number of SAEs?</td>
</tr>
<tr>
<td>Will sponsor pay for an adequate number of screen failures (especially important for difficult protocols)?</td>
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<tr>
<td>Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?</td>
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<tr>
<td>If necessary to store study records off-site, will sponsor pay?</td>
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7. Other

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