# PRESTUDY CHECKLIST

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

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

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| | 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? |

### 2. Population

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| | 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, and impaired adults with special consent issues? |
| | Do you expect a significant number of adverse events? (How ill is this population?) |

### 3. Protocol

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| | Is the protocol well designed? |
| | Is the protocol ethical? Will the IRB have problems with it? |
| | 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? (Dropouts may be more likely if the study drug becomes commercially available while the study is still underway.) |

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| | Is the study unusually long in duration? (Dropouts 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 case report 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**

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| | Are procedures frequent? |
| | Are procedures difficult? |
| | 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**

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| | Is 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? |
| | Is a draft consent form provided by the sponsor? (Staff-written consent forms take time.) |
| | 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? |

**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 submissions, 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: |
| | • Protocol amendments (may require consent form revisions)? |
| | • Reconsenting subjects? |
| | • Unanticipated monitoring visits? |
| | • Audits? |
| | • 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? |
| | If necessary to store study records off-site, will sponsor pay? |

**7. Other**

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| | Is adequate clinic and office space available? |
| | Are records storage facilities 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? |