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| **PROTOCOL FEASIBILITY TOOL** |

*Directions:* Responses to this form constitute the best estimate of resources and capability to fulfill the study requirements. Complete the form after reviewing the protocol and other available study materials. This form is intended to be used to guide the completion of the Protocol Feasibility Score Card.

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| PI:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_ \_\_ \_\_\_\_ | Trial:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Sponsor:\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | PHASE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_­­­­\_\_\_\_\_\_\_\_\_\_\_ |
| Enrollment Goal per Site:\_\_\_\_ \_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ | TOTAL ENROLLMENT FOR TRIAL:\_\_\_\_\_ \_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_ |
| Number of Sites:\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_ \_\_\_\_\_\_Global /US | GLOBAL ENROLLMENT START DATE:\_\_\_\_\_\_\_ \_\_\_\_ \_\_\_\_\_\_\_\_\_ |
| Estimated Start Date:\_\_\_\_\_ \_\_\_ \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ | ESTIMATED ENROLLMENT END DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_ |
| CRO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Type of trial: Device / Drug / Registry / Other |

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| POPULATION | Yes | No | Unk | NA |
| Do you have access to the subject population? |  |  |  |  |
| Is there a plan in place for identifying potential subjects? |  |  |  |  |
| Are the targeted subjects your patients? (PI clinic vs. other clinics) |  |  |  |  |
| Is the proposed enrollment goal realistic? |  |  |  |  |
| How many subjects could you enroll in one month? | Number:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| What is the screen failure ratio\_\_\_\_\_\_\_\_\_\_? Was this calculated in enrollment number? |  |  |  |  |
| Is the enrollment period realistic for this site? |  |  |  |  |
| Are particular inclusion/exclusion criteria prohibitive to recruitment?  |  |  |  |  |
| Do any current studies at your site compete for the same patient population? |  |  |  |  |

Additional Comments:

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| PROTOCOL DESIGN  | Yes | No | Unk | NA |
| Does the study have scientific merit? |  |  |  |  |
| Do study procedures conflict with current standard of care practices? |  |  |  |  |
| Is there a direct benefit to the potential subjects? |  |  |  |  |
| Is the study unusually long in duration? |  |  |  |  |

Additional Comments:

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| --- | --- | --- | --- | --- |
| PROTOCOL EXECUTION | Yes | No | Unk | NA |
| Are study procedures (frequency, discomfort, complexity) likely to impact participation? |  |  |  |  |
| Are study visits complex and/or present possible scheduling difficulties? |  |  |  |  |
| Are subject compliance problems likely, requiring time-consuming phone calls or other forms of communication? |  |  |  |  |
| Are subject materials (e.g., diaries, drug logs, questionnaires etc.) used? If so, do these materials require extensive time for staff transcription? |  |  |  |  |
| Are the Case Report Forms/Data Forms complex or lengthy (if available)?  |  |  |  |  |
| Is the data required typically documented routinely in the medical record? |  |  |  |  |
| Is necessary equipment available? If no, will the sponsor provide it?  |  |  |  |  |
| Are drug or device storage/accountability requirements burdensome? |  |  |  |  |
| Are all study procedures performed at this site? Can provisions be made for procedures that cannot be performed at this site? |  |  |  |  |

Additional Comments:

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| STAFF | Yes | No | Unk | NA |
| Does the investigator possess the time to oversee this study? |  |  |  |  |
| Does this study impact the physician office/clinic? If yes, explain below. |  |  |  |  |
| Is there sufficient research staff in place to coordinate the study? |  |  |  |  |
| Does this study require after hours or on call staffing? If yes, explain below. |  |  |  |  |
| If an inpatient study, will floor staff need to be involved? |  |  |  |  |
| Does this study impact ancillary departments/specialties (i.e., surgery, cath lab, radiology, lab, pharmacy, neurology)? If yes, consider actual impact on staff operations. |  |  |  |  |
| Is additional training required for physicians and/or staff (e.g., additional GCP or procedure training)? |  |  |  |  |

Additional Comments:

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| FINANCIAL IMPACT | Yes | No | Unk | NA |
| Does funding source's preliminary budget meet or exceed the estimated trial costs? |  |  |  |  |
| Does the funding source agree to pay for prescreening logs?  |  |  |  |  |
| Does the sponsor pay for screen failures (especially if high screen failure ratio is anticipated)? |  |  |  |  |
| Are there reimbursement and/or insurance issues to consider? If yes, explain below. |  |  |  |  |

Additional Comments:

Person completing the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_