**PROTOCOL FEASIBILITY ASSESSMENT CHECKLIST**

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| --- | --- |
| Protocol Title: |  |
| Sponsor: |  |
| CRO: (if applicable) |  |
| Test Article: |  |
| Trial Phase: |  |
| Investigator: |  |
| Department |  |
| Person Completing Form: |  |
| Date: |  |

1. **Scientific/Regulatory** 
   1. Does the study address a question of clinical and scientific relevance? (Do you think this study is scientifically meritorious?)
   2. What impact will this study have on patients?
   3. Do you think the patient population being studied will benefit from the study?
   4. Do you anticipate any IRB related issues with this protocol? If so, is there enough time for recruitment after the IRB approval process?
   5. Do you anticipate any MHH approval related issues with this protocol? If so, is there enough time for recruitment after the hospital approval process?
   6. Will this study require equipment be brought into the university and/or MHH?
   7. Do you anticipate other UT department approvals: Radiology/DII, BSC, COI, CRU; LBJ
   8. Would you be required to apply for an IND / IDE for this study? If so, do you have adequate resources to support your IND / IDE application?

***Notes/Comments:***

1. **Study Subjects**
   1. Will you be able to enroll the target number within the enrollment period?
   2. Is the eligibility criteria realistic (very restrictive)? (Consider screen failures. If you anticipate a very high screen failure rate, do check whether the sponsor will compensate for screen failures)
   3. Do you have the available patient pool that might meet the eligibility criteria?
   4. Will this study be competing for the same potential participants of the site’s other currently active stud(ies)?
      * If so, how will you determine which study the potential participant(s) will be enrolled in?
   5. Will it be necessary to contact other researchers to be co-investigators?
   6. Does this protocol involve recruiting vulnerable subjects?
   7. Are there any additional considerations for recruitment?
   8. Will the recruitment be done in the emergency department or the ICU?
   9. How many subjects are currently enrolled in the study (overall)? And do we have time to enroll sufficient subjects before the study closes?

***Notes/Comments:***

1. **Procedures/clinical assessments**
   1. Do you have experience conducting a similar research study in the past?
   2. Are frequent observations/procedures required?
   3. Are there multiple follow-up visits required? What is the study duration? For very long term studies, consider subject dropout rates and staff attrition.
   4. Are procedures/clinical assessments difficult?
   5. Are there special requirements for storage of biological samples?
   6. Are there special requirements for drug / device accountability? Does the drug need to be reconstituted – do you have access to a facility to do this?
   7. Are subject diaries being used? If so, does the study team need to transcribe them?
   8. Do you need special equipment? If so, how will you make these available?
   9. Do you have research staff with the time to conduct this trial? think you would need additional staff?
   10. Does this study require inpatient requirements and/or 24 coverage?
       * If so, does the team have the human resources/experience to conduct an inpatient study
       * If so, does the sponsor budget addresses the additional costs for an inpatient study (i.e. 24 hour coverage, off-hour lab sampling, IP dosing, in-patient nursing coverage, etc)
   11. Will there be external collaborators/departmental involvement necessary for the conduct of the study? If yes, consider the logistical and budgetary implications.

***Notes/Comments:***

1. **Documentation and Reporting**
   1. Will electronic CRFs be used? If so do you have the resources (personnel, hardware etc.)?
   2. Is concomitant medication documentation very complex and detailed?
   3. Are the adverse event reporting and documentation requirements too complicated?
   4. Is study article dispensing/accountability complicated?
   5. Are there any image transfer requirements as part of the study? If yes then is image redaction software capability offered by the sponsor or the study site?

***Notes/Comments:***

1. **Other considerations**
   1. Have you worked with this particular sponsor before? Was your experience with this sponsor satisfactory? If not, consider talking to your colleagues about this sponsor.
   2. For industry sponsored studies:
      * Has the sponsor obtained/registered the study in ClinicalTrials.gov with an NCT number?
      * Is the sponsor financially solvent?
   3. What does the monitoring schedule look like? Is it remote/in person? Is the monitoring frequency a hindrance or help? Is there a CRO involved? Does the monitoring plan meet the needs of the study and/or the department's capabilities?
   4. What are the local costs of participating (pharmacy, laboratory, staff training, CRU, LBJ, diagnostic/interventional imaging)?
   5. What will be the cost of staff time to conduct the study?
   6. Will the payment schedule and reimbursements meet operational costs?

***Notes/Comments:***

**Decision:**