**PROTOCOL FEASIBILITY ASSESSMENT CHECKLIST**

**[Complete this form when reviewing potential site participation in a collaborative research study or clinical trial.]**

**[Note, some questions may not be applicable to all study types/protocols.]**

|  |  |
| --- | --- |
| **Project title:** |  |
| **Department:**  |  |
| **Principle Investigator:** |  |
| **Documents reviewed:** | **Protocol / Consent documents / Agreement / Investigational Brochure /Other:**  |
| **Completed by:** |  |
| **RECOMMENDATION:** | [ ]  **Feasible** – move on with further consideration/negotiations/approval applications [ ]  **Not Feasible** – decline study |

|  |  |  |
| --- | --- | --- |
| **Scientific/Regulatory**  | **Answer / Comments** | **Is this a deal breaker? If ‘Yes’, is there any way to overcome the issue?** |
| Is the study of clinical and scientific relevance? (Do you think this study is scientifically meritorious?) | [ ]  Yes[ ]  No |  |
| How will participants be impacted from this study? | <add brief description> |  |
| Do you think the patient population being studied will benefit from the study?  | [ ]  Yes[ ]  No |  |
| Do you anticipate any ethical review related issues with this protocol? If so, is there enough time for recruitment after the ethical review approval process? | [ ]  Yes[ ]  No |  |
| Do you anticipate any MH governance approval related issues with this protocol? If so, is there enough time for recruitment after the hospital approval process? | [ ]  Yes[ ]  NoComments: |  |
| What type of study it? | [ ]  QA [ ]  Research[ ]  Registry [ ]  IIT Clinical trial[ ]  Commercially sponsored Clinical trial |  |
| Would you be required to apply for an CTN/CTX for this study? | [ ]  Yes[ ]  No |  |
| **Study Participants** | **Answer / Comments** | **Is this a deal breaker? If ‘Yes’, is there any way to overcome the issue?** |
| Does the study involve participants? | [ ]  Yes[ ]  NoComments: |  |
| Do you have the available patient / participant pool that might meet the eligibility criteria? | [ ]  Yes[ ]  NoComments: |  |
| Will you be able to enrol the target number within the enrolment period? | [ ]  Yes[ ]  NoComments: |  |
| Are the eligibility criteria realistic? (for clinical trials - consider screen failures. If you anticipate a very high screen failure rate, do you think you can meet the recruitment target?) | [ ]  Yes[ ]  NoComments: |  |
| Do you think you need help from others (i.e. physician colleagues) to participate in screening of patients to meet the recruitment target?  | [ ]  Yes[ ]  NoComments: |  |
| Are there competing studies that target the same patient population?  | [ ]  Yes[ ]  NoComments: |  |
| Does this protocol involve recruiting vulnerable participants?  | [ ]  Yes[ ]  NoComments: |  |
| Are there any additional considerations for recruitment?  | [ ]  Yes[ ]  NoComments: |  |
| Will the recruitment be done in emergency department or the ICU? | [ ]  Yes[ ]  NoComments: |  |
| **Procedures** | **Answer / Comments** | **Is this a deal breaker? If ‘Yes’, is there any way to overcome the issue?** |
| Do you have experience conducting a similar research study in the past? | [ ]  Yes[ ]  NoComments: |  |
| Are frequent observations/procedures required?If yes, will this pose staffing, timing, protocol compliance issues? | [ ]  Yes[ ]  NoComments: |  |
| Are observations/procedures required outside of standard working hours i.e. overnight, weekends?If yes, will this pose staffing, timing, compliance issues? | [ ]  Yes[ ]  NoComments: |  |
| Are there multiple follow-up visits required? What is the study duration? For very long-term studies, consider subject dropout rates and staff attrition. | [ ]  Yes[ ]  NoComments: |  |
| Are procedures/clinical assessments difficult? | [ ]  Yes[ ]  NoComments: |  |
| Are there special requirements for storage of biological samples?Can the sampling and storage needs be met? | [ ]  Yes[ ]  NoComments: |  |
| Are there special shipping and handling instructions such as dry ice or special containers? Will these be provided by a collaborator/sponsor? | [ ]  Yes[ ]  NoComments: |  |
| Are there special requirements for drug / device accountability? | [ ]  Yes[ ]  NoComments: |  |
| Does the drug need to be reconstituted – do you have access to a facility to do this? | [ ]  Yes[ ]  NoComments: |  |
| Are participant diaries being used? If so, does the study team need to transcribe them? | [ ]  Yes[ ]  NoComments: |  |
| Do you need special equipment?If so, how will you make these available?  | [ ]  Yes[ ]  NoComments: |  |
| Do you have enough research staff with the time and skills to conduct this study? Do you think you would need additional staff? | [ ]  Yes[ ]  NoComments: |  |
| **Documentation and Reporting** | **Answer / Comments** | **Is this a deal breaker? If ‘Yes’, is there any way to overcome the issue?** |
| Is this a retrospective data collection study? | [ ]  Yes[ ]  No |  |
| Is the data collected more than standard of care data? | [ ]  Yes[ ]  No |  |
| Is the data collection schedule complicated/burdensome? | [ ]  Yes[ ]  No |  |
| Do you have permission to collect the data (from all internal and external sources as required) | [ ]  Yes[ ]  No |  |
| Is there adequate storage space for paper and electronic files for the entire active and archiving phases of the study? | [ ]  Yes[ ]  No |  |
| For clinical trials – * Will electronic CRFs be used? If so, do you have the resources (personnel, hardware etc.)?
 | [ ]  Yes[ ]  No |  |
| * Is concomitant medication documentation very complex and detailed?
 | [ ]  Yes[ ]  No |  |
| * Are the adverse event reporting and documentation requirements too complicated?
 | [ ]  Yes[ ]  No |  |
| **Other considerations** | **Answer / Comments** | **Is this a deal breaker? If ‘Yes’, is there any way to overcome the issue?** |
| Have you worked with this collaborator/sponsor before? Was your previous experience satisfactory? If not, would you consider working with them again? | [ ]  Yes[ ]  No Comments: |  |
| How does the monitoring schedule look? (Frequent monitoring helps keep the study in order, but may require a lot of staff time) | [ ]  Yes[ ]  NoComments: |  |
| Will the collaborator/sponsor pay for patients who are screened but determined not to be eligible? If they will not pay, how will the screen failure cost be recovered?  | [ ]  Yes[ ]  NoComments: |  |
| Will the payment schedule and reimbursements meet your operational costs? | [ ]  Yes[ ]  NoComments: |  |
| Would you like to be part of this study? | [ ]  Yes[ ]  NoComments: |  |
| Will there be student researchers involved at this site. | [ ]  Yes[ ]  NoComments: |  |