| *Please assess each item as realistically as possible in terms of our ability and capacity to do this study. Add relevant details in the Comments section.* |
| --- |
| **Section 1: General Considerations** | **Yes, No or** **More sponsor info needed** | **Relevant Details/Comments**  |
| Do we have any competing studies? | [ ]  Yes [ ]  No  |  |
|  If so, do we have enough patients to cover all studies? | [ ]  Yes [ ]  No  |  |
| Do we have sufficient staff to perform this study? | [ ]  Yes [ ]  No  |  |
| Who will be the PI and lead RC at our site? |  |
| Where will the study visits occur (clinic, GCRC, other)? |  |
|  Will there be room availability for the visits? | [ ]  Yes [ ]  No |  |
| What is the anticipated start date? | [ ]  More info |  \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_ |
| Do we have all of the required equipment/resources to perform this study (e.g. Centrifuge, freezer, storage space, research pharmacy, etc)?  | [ ]  Yes [ ]  No [ ]  More info  |  |
|  If NOT, will the sponsor provide the required equipment? | [ ]  Yes [ ]  No [ ]  More info |  |
| If a preliminary budget has been provided, does it appear to be adequate? | [ ]  Yes [ ]  No | [ ]  Not provided |
| If we have worked with this sponsor before are there are any concerns about working with them again?  | [ ]  Yes [ ]  No [ ]  More info |  |
| If we have worked with this CRO before are there are any concerns about working with them again? | [ ]  Yes [ ]  No [ ]  More info |  |
| How many other vendors will our site work with directly (e.g. IVRS, lab) and will it impact the amount of time we spend on the study? | [ ]  Yes [ ]  No [ ]  More info |  |

| **Section 2: Scientific Evaluation** |  | **Relevant Details/Comments** |
| --- | --- | --- |
| Are the specific aims and corresponding hypotheses clearly stated? | [ ]  Yes [ ]  No |  |
| Are the proposed outcome measures appropriate to answer the scientific question? | [ ]  Yes [ ]  No |  |
| Is the study design (visit schedule, procedures, and statistics) appropriate for the questions posed? | [ ]  Yes [ ]  No |  |
| Are the hypotheses being tested providing important knowledge to the field? | [ ]  Yes [ ]  No |  |
| If the study is designed as a comparative trial, is there clinical equipoise? | [ ]  Yes [ ]  No |  |
| Is there adequate discussion and justification of the proposed sample size? | [ ]  Yes [ ]  No |  |
| Does the study include appropriate safety testing? | [ ]  Yes [ ]  No |  |
| Is there adequate preliminary data to justify the proposed research? | [ ]  Yes [ ]  No |  |
| Is the IRB likely to have any issues with any aspect of this study? | [ ]  Yes [ ]  No |  |
| Will our patients benefit from this study? (Comment on how patients will benefit) | [ ]  Yes [ ]  No |  |

| **Section 3: Study Procedures** | **Yes, No or More sponsor info needed** | **Relevant Details/Comments** |
| --- | --- | --- |
| How many visits per subject are required and how frequently do they occur? | [ ]  More info | Visit # and frequency:  |
| Are there any inpatient visits required? | [ ]  Yes [ ]  No [ ]  More info  |  |
| Is study drug administration and/or dispensing complicated?  | [ ]  Yes [ ]  No [ ]  More info  |  |
| Are there any complicated or difficult procedures?  | [ ]  Yes [ ]  No [ ]  More info  |  |
| Is any special training or specialized equipment required?  | [ ]  Yes [ ]  No [ ]  More info  |  |
| Are there any invasive procedures (other than blood draws)?  | [ ]  Yes [ ]  No [ ]  More info  |  |
| Are any specialists required that are not part of our usual team (audiologist, other)?  | [ ]  Yes [ ]  No [ ]  More info  |  |
| Are there any non-lab procedures that will be reported centrally (e.g. ECGs)? | [ ]  Yes [ ]  No [ ]  More info |  |
| Are lab assays being done in-house or by central lab? | [ ]  More info  | [ ]  In-House [ ]  Central Lab [ ]  Both |
| Will specimen processing and storage be required? | [ ]  Yes [ ]  No [ ]  More info  |  |
| Will specimens need to be shipped (e.g. requiring dry ice, certification to ship biological specimens, or impacting timing of clinic visits)? | [ ]  Yes [ ]  No [ ]  More info  |  |
| How will data be captured – paper or electronic CRFs? | [ ]  More info  | [ ]  Paper [ ]  eCRF  |
| Are there any other factors that may make this study difficult to perform?  | [ ]  Yes [ ]  No [ ]  More info  |  |

| **Section 4: Study Population** | **Yes, No or More sponsor info needed** | **Relevant Details/Comments**  |
| --- | --- | --- |
| Will our patients be generally interested in this study? | [ ]  Yes [ ]  No  |  |
| Will adults (≥ 18 years old) be enrolled? | [ ]  Yes [ ]  No |  |
| Will infants, children (< 18 years old) be enrolled? | [ ]  Yes [ ]  No |  |
| Estimate the number of study subjects we could recruit/enroll at our site vs. the number required/requested by the sponsor: | [ ]  More info | # sponsor requests: \_\_\_\_\_\_ # from our site:­­­­\_\_\_\_\_\_  |
| What specific eligibility or procedural requirements will limit enrollment at our site (e.g. placebo, number of visits, inconvenient schedule, invasive procedures, study expected to enroll over holidays, etc.)?  | [ ]  More info | Issues: |
| Should we consider recruiting subjects through site referrals?  | [ ]  Yes [ ]  No  |  |
|  If yes, will the sponsor provide additional compensation for travel?  |  |  |
| Can we enroll our subjects at the projected enrollment rate?  | [ ]  Yes [ ]  No [ ]  More info | Rate:  |
| Can we enroll our subjects in the projected enrollment period?  | [ ]  Yes [ ]  No [ ]  More info | Planned enrollment period: |

|  |  |  |
| --- | --- | --- |
| **Section 5: Overall Assessment** |  | **Comments** |
| Do you/we recommend that this study be conducted at our site? | [ ]  Yes [ ]  No |  |
| **Comments:**Is there any additional information that would be required before making a final recommendation?**What are the risks if we conduct this study at our site?**  |
| ***Completed by:***Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

If your initial interest in a study has been confirmed, but insufficient study details have been provided for you to determine if you can successfully recruit subjects into the study, you may want to request additional information from the sponsor. An example email is provided here:

***In order for our study team to better assess our capability and interest in conducting your trial at our institution, we would appreciate your responses to a few questions:***

* What is the anticipated start date, enrollment period?
* Based on the study synopsis it was unclear if special equipment would be required. Please clarify by providing a list or confirming the following: (list: e.g. high-speed centrifuge, spirometer for centralized reading, ECG equipment)
* Does study drug require any reconstitution or special handling at the study site?

Thank you in advance for your help.

Name and contact information