The purpose of the Clinical Trial Feasibility Review Process is to meet expectations in assessing research trial feasibility at Emory University. The feasibility review involves a proactive review to determine enrollment barriers and operational requirements. A feasibility review must occur prior to protocol approval and submission for pre-award approvals.

**INSTRUCTIONS:**

Please complete form for all trials (*interventional and non-interventional).*

**Protocol Title:**

**Principal Investigator:**

**Clinical Research Coordinator(s):**

|  |
| --- |
| 1. **PATIENT ACCRUAL & PI WORKLOAD**

**(Completed by *[Research Administrator or Designee]* & Investigator)** |
| **Patient Population Seen at University(TriNetX data):****Overall Target Accrual Goal:** **Overall Accrual** *(if available)***:** |
| 1. **CLINICAL OPERATIONS CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Does the [PI] expect staffing to be adequate and experienced to conduct the trial once opened?Are personnel required to conduct special procedures or efficacy measures? Does the [PI] anticipate any staffing challenges in operationalizing this protocol at participating sites? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **REGULATORY CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to complete a timely study start-up process? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is current staffing adequate and experienced to maintain ongoing regulatory activities once the trial is activated? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **FINANCIAL CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Does [Investigator] have financial resources to support the trial if it is unfunded or underfunded? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are special equipment or supplies required and provided by the Sponsor? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **QUALITY AND TRAINING CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Is current staffing adequate and experienced to support the quality and education necessary for trial conduct? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| If this is a multi-site trial with an Emory PI serving as the main study PI, are appropriate monitoring resources in place?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **ENROLLMENT CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are the inclusion & exclusion criteria reasonable to meet the accrual goal?  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Do we have access to the right patient population? *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **PROTOCOL CONSIDERATIONS**
 |  |  |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are there competing trials? If so, are there enough eligible patients to support this trial? Provide justification for competing trials. *(See section A for accrual considerations.)* | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is the protocol similar to previously conducted studies? If so, were the previous studies successfully completed? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Is specialized equipment required? Is there appropriate training and space for the equipment. If yes, please comment.  | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will special procedures require evaluations or testing outside of regular clinic hours? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Does the staff/study team require special training on the protocol? (i.e., procedural, biosafety concerns) | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Have you successfully worked with this Sponsor in the past? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| 1. **ANCILLARY SERVICES CONSIDERATIONS**
 |
|  | **YES** | **NO** | **NA** | **UNK** | **Comments** |
| Are there special imaging requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will in-patient resources be required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Will special laboratory equipment and personnel be adequate to conduct the protocol? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are extended hours required? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special ophthalmology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special outpatient requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special research pharmacy requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special pathology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special cardiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there dermatology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there audiology requirements? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| Are there special protocol requirements that need consideration? | [ ]  | [ ]  | [ ]  | [ ]  |  |
| **Completed by Research Manager** | **Low****(no feasibility challenges)** | **Moderate****(some feasibility challenges)** | **High****(many feasibility challenges)** |
| What impact do the responses above have on feasibility? | [ ]  | [ ]  | [ ]  |
| **Additional Comments:** |  |  |  |

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| **SIGNATURES** |
|  |  |  |
| Research Administrator Signature |  | Date |
|  |  |  |
| Principal Investigator Signature |  | Date |